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Self-stigma, decisional capacity and personal recovery in psychosis

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DClinPsychol Declaration of Own Work

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Research Portfolio Abstract

Introduction: This research portfolio set out to examine service user defined recovery in psychosis. A systematic review was undertaken to examine the evidence-base for the effectiveness of psychosocial interventions on personal recovery, empowerment and other recovery-related outcomes. An empirical study was conducted to examine the relationships between self-stigma, decisional capacity for treatment and personal recovery in service users with psychosis.

Methods: A review of published literature identified ten randomised controlled trials investigating the effects of psychosocial interventions on personal recovery. A narrative synthesis was reported for findings relating to primary and secondary outcomes, and standardised effect sizes were calculated to quantify within-group change from pre-to post-intervention and follow-up. Studies were assessed for risk of bias. The empirical study recruited twenty-four participants with diagnoses of non-affective psychosis. Semi-structured interviews and self-report measures were administered to assess self-stigma, decisional capacity for treatment, psychopathology, emotional distress and personal recovery.

Results: A small number of studies found that recovery-focused psychosocial interventions improved personal recovery. There were more consistent effects on psychiatric symptoms, functioning and depression. The empirical study found that self-stigma and personal recovery were associated with each other. Large effect sizes were found for the associations between self-stigma and symptoms. These associations persisted when controlling for personal recovery scores. Understanding of treatment

was predicted by excitement symptoms, but no other prediction model emerged for decisional capacity.

Conclusion: Taken together, the systematic review and empirical project support service user definitions of recovery which highlight the role of psychosocial factors. The systematic review found some evidence for the role of recovery-focused psychosocial interventions in improving personal recovery. Further research is needed so that interventions specifically targeting the processes in personal recovery can be developed. The findings from the empirical project suggested that interventions designed to overcome self-stigmatising beliefs and reduce emotional distress are likely to improve personal recovery outcomes in psychosis. More research is needed to develop a broader conceptualisation of decisional capacity in psychosis, to support the active participation of service users in their recovery journey.

Keywords:

Psychosis, clinical recovery, personal recovery, self-stigma, decisional capacity

Chapter 1: Systematic Review

What works to improve service user defined recovery in psychosis? A systematic review.

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Purpose. To examine the evidence-base for the effectiveness of psychosocial interventions in improving user-defined personal recovery and recovery related outcomes in psychosis.

Method. A systematic review of published literature was conducted. Randomised controlled trials investigating the effects of psychosocial interventions on personal recovery were identified. Studies were assessed for risk of bias. Study findings regarding between-group differences at post-intervention and follow-up were summarised. Standardised effect sizes were calculated to quantify the change within groups from baseline to post-intervention and from baseline to follow-up on the primary and secondary outcomes.

Results. Ten studies met inclusion criteria. A small number of studies found that psychosocial interventions significantly improved personal recovery and empowerment outcomes compared to routine care. Half of the studies found within-group improvement on personal recovery following the psychosocial intervention, with robust within group effects for individual cognitive therapy (CT). There were more consistent effects of psychosocial interventions on the secondary outcomes e.g. psychiatric symptoms, functioning and depression. The small number of studies and risk of bias suggest findings should be interpreted with caution.

Conclusions. Research into how interventions can improve personal recovery in psychosis is still in its infancy. The current evidence signals that recovery-focused interventions may improve personal recovery, and may have more consistent effects on

recovery-related secondary outcomes. Further research is needed so that interventions specifically targeting the processes in personal recovery can be developed.

Practitioner points

- The limited evidence available signals that recovery-focused psychosocial interventions can help to improve service user defined recovery.

- Manualised cognitive therapy for psychosis, modified to address issues of internalised stigma, may have a more robust effect on personal recovery improvement than other psychosocial interventions, but further studies are needed to support this.

- Measures of personal recovery should be used to track changes in the service user's experience of recovery, to inform future care planning and to ultimately enhance service user engagement.

Introduction

Recovery from severe mental illness is a complex process with ongoing debate regarding definitions of recovery (Schrank & Slade, 2007). Until now, the 'clinical recovery' model of mental health care, with its focus on diagnostic classifications of symptoms, has dominated how individuals with psychosis have been understood and treated. This approach emphasises the management of psychiatric symptoms and a return to 'normal functioning' (Davidson, O'Connell, Tondora, Lawless, & Evans, 2005). However, clinical definitions of recovery have been criticised for treating recovery as an endpoint, predicated on symptom remission (Davidson et al., 2005). Furthermore, clinical diagnosis has been implicated in contributing to the stigma experienced by service users, and health professionals are at risk of compounding this by viewing service users as groups of psychiatric diagnoses rather than individuals (Corrigan, 2007).

In contrast, service users advocate that recovery involves overcoming psychological and social consequences of a mental health diagnosis, rather than reducing the symptoms of illness per se – an approach that has been defined as 'personal recovery' (Davidson et al., 2005; Schrank & Slade, 2007; Slade, 2009). This conceptualisation of recovery, evolved from service user narratives, challenges the traditional clinical recovery model of care. Given the uniqueness of recovery to each individual, there has been difficulty reaching a clear definition of personal recovery within the service user community (Leamy, Bird, Le Boutillier, Williams, & Slade, 2011). However, reviews of service user narratives highlight common factors and values. Personal recovery has been characterised as a journey (Leamy et al., 2011) that has a number of stages through which service users develop awareness and acceptance of their disorder

(Schrank & Slade, 2007). A review of the personal recovery literature identified five processes as being integral to the recovery journey: connectedness; hope and optimism about the future; identity; meaning in life; and empowerment (Leamy et al., 2011). A subsequent review supplemented these processes with an additional dimension emphasising the struggles that are experienced in recovery, related to living with a mental health disorder, and likely impacted upon by social inequality (Stuart, Tansey, & Quayle, 2016).

Empirical research has demonstrated that personal recovery is associated with self-esteem, empowerment, social support and quality of life (Corrigan, Giffort, Rashid, Leary, & Okeke, 1999). Furthermore, there is evidence that gaining control over psychiatric symptoms enhances personal recovery (Corrigan et al., 1999; Macpherson et al., 2015). However, service users reported a greater level of consensus on a number of psychosocial factors essential for personal recovery, such as self-esteem and satisfaction with life, than on the management of symptoms (Law & Morrison, 2014). In contrast to clinical recovery, the personal recovery literature highlights that recovery, as defined by service users, can take place in the absence or presence of symptoms.

Encouragingly, over recent years policy makers have endorsed the personal recovery approach and have called for mental health agencies to offer services that empower service users to take control of their lives and maximise their wellbeing (Macpherson et al., 2015; Schrank & Slade, 2007). Despite this, psychosocial interventions for people with psychosis have predominantly been evaluated according to their effectiveness in producing symptomatic and functional change. However, if recovery involves far more

than symptom remission and resolution of functional deficits, as indicated by the personal recovery literature, then these methods of evaluation are unlikely to go far enough to detect changes in outcomes that are valued by service users. As others have pointed out (e.g. Bradstreet, 2016), continued reliance on clinical recovery outcomes poses a risk of service providers withdrawing interventions that give rise to meaningful change for service users but cannot be shown to produce symptomatic change, or may even result in service users facing early discharge from services when symptomatic recovery has been reached while other processes integral to personal recovery have not been addressed. Thus, in order for service providers to align their services with the broader values of recovery that are important to service users, they may want to consider effectiveness according to personal recovery outcomes. Shifting from service-imposed clinical recovery to user-defined personal recovery will likely require significant cultural change in mental health organisations (Schrank & Slade, 2007).

To facilitate this change, psychometric instruments have been developed and evaluated, often in consultation with service users, to measure personal recovery outcomes. Reviews of these instruments have been published over recent years (e.g. Cavelti, Kvrgic, Beck, Kossowsky, & Vauth, 2012; Law, Morrison, Byrne, & Hodson, 2012; Shanks et al., 2013; Sklar, Groessl, O'Connell, Davidson, & Aarons, 2013). Earlier instruments, such as the Recovery Assessment Scale (RAS; Giffort et al., 1995) were developed to understand and measure personal recovery across the spectrum of severe mental illness, however an instrument has now been developed specifically for personal recovery in psychosis (Questionnaire on the Process of Recovery, QPR; Neil at al., 2010). Consequently, researchers have called for such measures to be used

routinely in the evaluation of psychosocial interventions (Andresen, Caputi, & Oades, 2010; Macpherson et al., 2015; Neil et al., 2010).

In summary, recovery from the perspective of service users, defined as personal recovery, encompasses a broad range of psychosocial factors not taken into account by clinical definitions of recovery. Recognition of service users' lived experiences of recovery and endorsement of psychosocial care in mental health policy has the potential to change the landscape of mental health care for service users with psychosis. It seems timely to review the existing literature to establish what psychosocial interventions are effective in producing personal recovery outcomes that are of value to service users. The present review aimed to address this gap in the research by asking the following research questions:

1) Do recovery-focused psychosocial interventions improve user-defined recovery and empowerment for individuals with psychosis?

2) Do recovery-focused psychosocial interventions improve secondary outcomes, including psychiatric symptoms, depression, anxiety, functioning and quality of life?

3) What are the methodological sources of bias in the literature?

Method

The current review was written in PRISMA format (Appendix 2).

Search

An electronic search of the Cochrane Central Register of Controlled Trials (CENTRAL), EMBASE, OVID MEDLINE (R), PsycINFO and Web of Science databases was undertaken using the following terms: (psychosis OR schizophrenia OR schizotypal disorder OR schizoaffective disorder OR delusional disorder OR severe mental illness OR serious mental illness) AND (recovery OR “personal recovery” OR “consumer recovery” OR “mental health recovery” OR “mental illness recovery”) AND (randomised controlled trial or randomized controlled trial). The search was limited to studies listed since 1995 (the inception of the RAS personal recovery measure). Searches were also run on the titles and abbreviations of the two personal recovery outcome measures of interest to this review: “Recovery Assessment Scale” OR “RAS” and “Questionnaire on the Process of Recovery” OR “QPR”. The original citations for both outcome instruments were entered into the Google Scholar search engine to identify, and screen for eligibility, studies that had cited these measures. Hand searches of the reference lists of included studies were performed to identify any further studies not returned in the electronic searches.

Study selection

Inclusion criteria

1) Study design

   Studies were included if they were randomised controlled trials (RCTs), including cluster RCTs, reported in English language. Blinded and non-blinded trials were eligible for inclusion, as were those conducted in outpatient and inpatient settings.

2) Participants

   Studies were included if participants were adults and at least 50% of study participants had a diagnosis of schizophrenia, schizoaffective disorder or delusional disorder.

3) Interventions

   Included studies reported outcomes for recovery-focused psychosocial interventions. These included psychological therapy, skills training, education, psycho-education, peer support and family interventions. Interventions delivered in individual, group, face-to-face or remote formats, and those that were facilitated as well as those that were not facilitated, were eligible for review.

4) Comparisons

Studies had a comparison group that involved either treatment as usual (TAU), an alternative intervention, a placebo-type treatment (e.g. befriending), or placement on a waiting-list for the duration of the intervention.

5) Outcome measures

Studies included either the RAS or QPR as an outcome measure. These instruments were selected based on findings from earlier systematic reviews which found them to be the most psychometrically valid and reliable outcome measures of personal recovery currently available, with the greatest acceptability to service users (Law et al., 2012; Shanks et al., 2013; Sklar et al., 2013).

Exclusion criteria

Studies were excluded if the intervention being evaluated was pharmacological or was deemed to be predominantly sociological (e.g. employment or housing programmes). There were no limitations on the basis of drop-out, missing data, or length of follow-up, given the preliminary stage of this research.

Pre-registration of review protocol

The review protocol was published in January 2016 on the PROSPERO International Prospective Register of Systematic Reviews, Registration number: CRD42016032910 (Lynch, 2016).

Data extraction and outcomes

The Cochrane Collaboration Data Collection Form for Intervention Reviews: RCTs (Higgins & Green, 2011) was used to evaluate study eligibility and for data extraction from included studies (Appendix 3). Reasons for studies excluded from the review were documented. For included studies, information was extracted regarding the study location, characteristics of participants, types of interventions and comparison groups, outcome measures, length of follow-up, type of analysis and main study findings. Group means, standard deviations and number of participants at baseline, end of treatment and follow-up were extracted for all available outcomes relevant to the review. Within-group effect sizes were calculated to indicate the magnitude of change observed from pre- to post-intervention and follow-up on each of the relevant outcomes using an online calculator, (http://campbellcollaboration.org/escalc/html/EffectSizeCalculator-SMD1.php). Due to the heterogeneity of the interventions involved, effect sizes of between-group differences across studies on each of the outcomes of interest to this review were not analysed. The magnitude of pre- to post-intervention and pre- to follow-up effects were considered according to Cohen's criteria of small, medium and large effects of 0.2, 0.5 and 0.8, respectively (Cohen, 1992).

Risk of bias

Methodological quality of the included studies was assessed using the Cochrane Collaboration Risk of Bias tool (Higgins & Green, 2011). This assessment tool covers the domains of sequence generation, allocation concealment, blinding, selective outcome reporting, and incomplete outcome data. The risk of bias for each domain was rated as high, low or unclear. An unclear risk of bias rating was applied where there

was insufficient detail of procedures used to inform a judgement. A second rater randomly selected and independently assessed for risk of bias 40% of the included studies. Inter-rater reliability was calculated, Kappa = 0.659 ($p < 0.001$), suggesting a good degree of agreement across raters. Discrepancies were resolved by discussion.

Results

Study selection, design and characteristics

The search strategy is outlined in Figure 1. After title, abstract and full text review, ten randomised controlled trials were identified as being eligible for inclusion in the review. The reasons for studies excluded following full-text review (*n*=119) are documented in Appendix 4. Table 1 shows characteristics and demographics of the included studies. Studies were published between 2009 and 2016. Three studies took place in the United Kingdom, two in the United States of America, and one each in Canada, Sweden, Switzerland, Denmark and Germany. All studies were RCTs; one (Slade et al., 2015) was a cluster RCT evaluating the effect of a psychosocial intervention delivered at team level, and two studies (Morrison et al., 2016; Schnackenberg, Fleming, & Martin, 2016) were described as pilot RCTs to determine the feasibility of the psychosocial interventions being evaluated. Seven studies used diagnostic criteria to confirm participants' diagnoses at trial entry; four studies used ICD-10 and three studies used DSM-IV. The remaining three studies did not report the use of any diagnostic criteria. Sample size of the studies varied from 22 to 403 participants, with a total of *n*=935 participants, including 463 participants in the intervention groups and 442 participants in the control groups. Mean ages ranged from 31.47 to 47.70 years.

Figure 1. PRISMA Flow Diagram

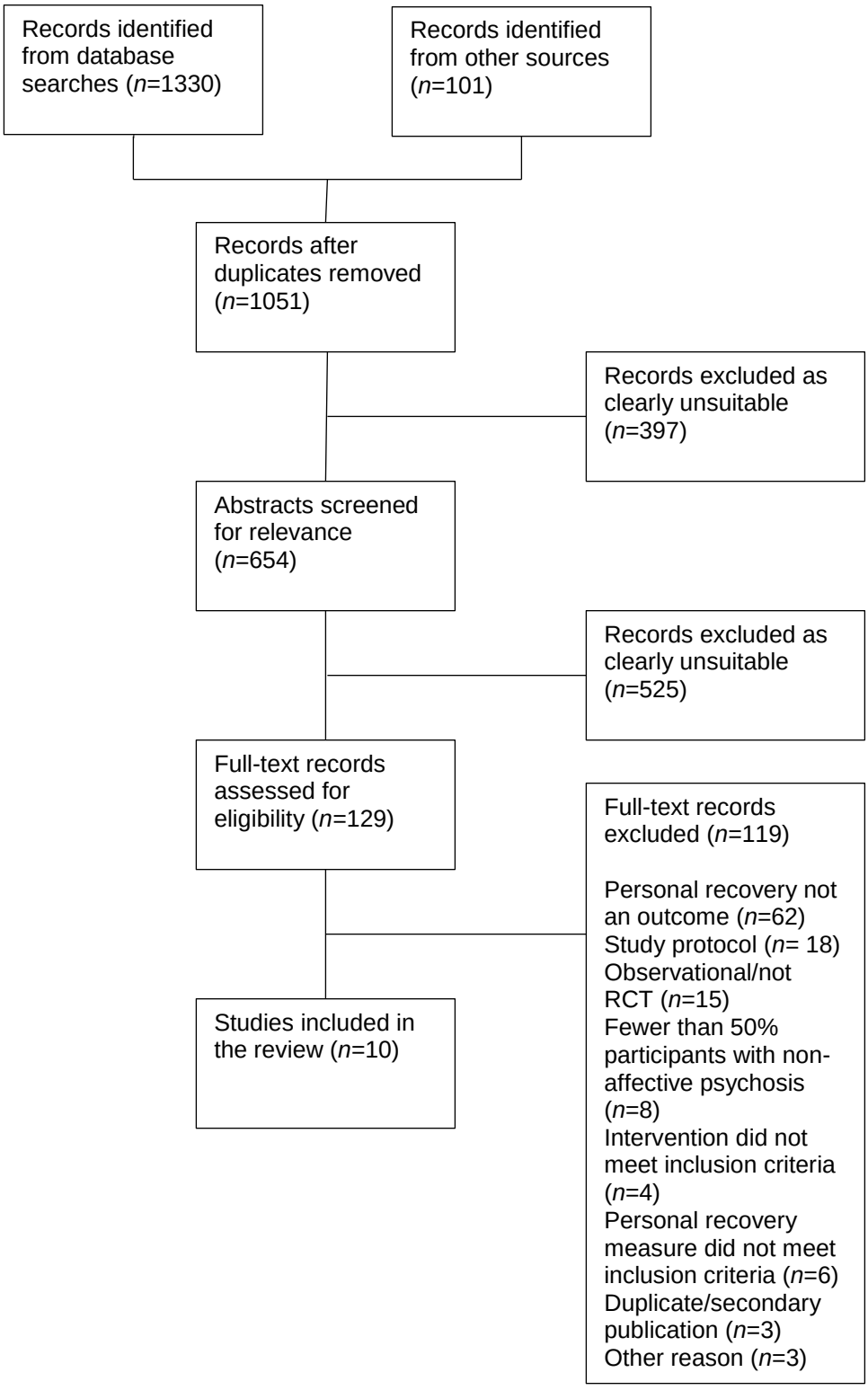

Table 1. Study characteristics and baseline demographics

Study, country	Sample characteristics	Intervention	Control	Baseline demographics								Post-intervention (months)	Follow-up (months from baseline)
				Intervention				Control					
				N	Mean age (yrs) (SD)	Gender (F/M)	Diagnosis	N	Mean age (SD)	Gender (F/M)	Diagnosis		
Barbic et al. 2009, Canada	DSM-IV schizophrenia, schizoaffective disorder, schizophreniform disorder, delusional disorder, or bipolar disorder; recipients of ACT for more than 6 consecutive months; outpatients; aged 18-60.	RW group intervention + TAU; weekly sessions; 2 hour duration; 12 week intervention period; 7-9 participants in each group.	TAU alone	16	44.69 (9.62)	5/11	Schizophrenia related, n=12 Bipolar, n=4	17	44.58 (8.05)	6/11	Schizophrenia related, n=14 Bipolar, n=3	3	None
Fardig et al. 2011, Sweden	DSM-IV schizophrenia or schizoaffective disorder; outpatients of six psychiatric rehabilitation centres.	IMR group intervention + TAU; weekly sessions; 1 hour duration; 9 month intervention period; 3-4 participants in each group.	TAU alone	21	40.38 (6.76)	8/13	Schizophrenia, n=16 Schizoaffective, n=5	20	40.45 (6.44)	11/9	Schizophrenia, n=16 Schizoaffective, n=4	9	21

Huguelet et al. 2011, Switzerland	ICD-10 schizophrenia or other nonaffective psychoses; psychiatry clinic outpatients.	Individual spiritual assessment + TAU; 90 minute training session for psychiatrists on spiritual assessment; psychiatrist carries out semi-structured interview with participant; followed up by supervision session with study authors; spiritual assessment informs follow-up care offered by psychiatrist.	TAU alone	42	42 (11)	16/26	NR	42	42 (9)	17/25	NR	None	3

Green et al. 2013, USA	Identified on a database as having diagnoses of bipolar disorder, schizophrenia, or schizoaffective disorder (diagnostic criteria not specified); outpatients recruited from a not-for-profit integrated health care system by responding to a study invitation letter.	PtR group intervention; weekly sessions; 2 hour duration; 10 week intervention period.	Delayed intervention (received the workbook after the trial)	Reported only for sample as a whole: Mean age (SD): 44.2 (9.8) Gender (F/M):17/13 Diagnoses: Schizophrenia spectrum disorder, n=15 (50%); Bipolar disorder, n=11 (37%) Depression, n=3 (10%)								3	6
				18				12					
Morrison et al. 2014, UK	ICD-10 schizophrenia, schizoaffective disorder, or delusional disorder, or met entry criteria to a Psychosis EIS; at least 6 months without antipsychotic drugs and continuing symptoms or had never received antipsychotics and had chosen not to;	Individual CT + TAU + regular monitoring; 26 weekly sessions; 1 hour duration; 4 booster sessions over a further 9 months duration.	TAU + regular monitoring	37	32.95 (13.11)	20/17	Reported for sample as a whole: Schizophrenia, n=68 Schizoaffective, n=2 Persistent delusional disorder, n=3 Psychosis not otherwise specified, n=1	37	29.68 (11.95)	15/22	Reported for sample as a whole: Schizophrenia, n=68 Schizoaffective, n=2 Persistent delusional disorder, n=3 Psychosis not otherwise specified, n=1	9	12, 15, 18

	contact with mental health services; outpatients.												
Salyers et al. 2014, USA	DSM-IV schizophrenia or schizoaffective disorder; receiving outpatient services at a veterans medical centre or community mental health centre.	IMR group intervention + TAU; weekly sessions; 2 hour duration; 9 month intervention period; less than 8 participants in each group.	Active control problem solving group (non-structured) + TAU; weekly sessions; 9 month period.	60	Whole sample mean (SD) = 47.7 (8.9)	14/46	Schizophrenia, n=27 Schizoaffective, n=33	58	Whole sample mean (SD) = 47.7 (8.9)	10/48	Schizophrenia, n=27 Schizoaffective, n=31	9	18
Jorgensen et al. 2015, Denmark	ICD-10 schizophrenia or schizoaffective disorder; receiving outpatient services at a hospital psychiatric clinic.	Individual GSD-SZ training + TAU; 10 sessions; 30-60 minutes duration; 6 month intervention period.	TAU alone	50	35.4 (12.2)	27/23	Schizophrenia, n=45 Schizoaffective, n=5	51	39.6 (12.7)	27/24	Schizophrenia, n=48 Schizoaffective, n=3	6	12

Slade et al. 2015, UK	Primary diagnosis of schizophrenia, schizoaffective disorder or bipolar disorder (diagnostic criteria not specified); receiving outpatient services at one of two NHS mental health trusts.	REFOCUS team level intervention + TAU (n=210) (14 teams)	TAU alone	210 - (14 teams)	44.87 (10.22)	78/131	NR	193 - (13 teams)	42.99 (11.56)	66/127	NR	12	None
Morrison et al. 2016, UK	ICD-10 schizophrenia, schizoaffective disorder, or delusional disorder, or met entry criteria to an Early Intervention Psychosis Service; high level of internalised stigma as defined by a score > 60 on ISMI-R; outpatients referred by CMHT, EIS, Assertive Outreach or Criminal Justice Liaison.	Individual CT + TAU + monitoring; maximum of 12 sessions; 1 hour duration; 4 month intervention period.	TAU + 3 monitoring assessments	Diagnoses reported only for sample as a whole: Schizophrenia, n=10 Schizoaffective, n=1 Bipolar with psychotic features, n=4 First episode of psychosis, n=14								4	7
				15	39.00 (13.50)	3/12		14	29.36 (10.02)	3/11			

Schnackenberg et al. 2016, Germany	Voice hearers with distress levels >= 4 severity rating on BPRS-E; did not need to have a psychiatric diagnosis to be included; diagnostic criteria not used; routine psychiatric setting; outpatients.	Individual EFC + TAU; 2-3 sessions per month; 45-60 minutes duration; 44 week intervention period.	TAU + 45-60 minutes 1-to-1 time with MHPs on 2-3 occasions per month.	Demographics reported only for participants included in the analysis:								11	None
				7	44.14 (9.49)	3/4	Schizophrenia, n=6 Schizoaffective, n=1	5	40.20 (11.32)	2/3	Schizophrenia, n=5		

Note: ACT, Assertive Community Treatment; BPRS-E, Brief Psychiatric Rating Scale - Expanded; CMHT, Community Mental Health Team; CT, Cognitive Therapy; DSM-IV, Diagnostic and Statistical Manual for Mental Disorders – Fourth Edition; EFC, Experience-Focused Counselling; EIS, Early Intervention Service; ICD-10, International Classification of Diseases – Tenth Revision; IMR, Illness Management and Recovery; ISMI-R, Internalised Stigma for Mental Illness Scale – Revised; GSD-SZ, Guided Self-Determination for Schizophrenia; TAU, Treatment as usual; MHPs, Mental Health Practitioners; NHS, National Health Service; NR, Not reported; PtR, Pathways to Recovery Workbook; RW, Recovery Workbook; SD, Standard deviation.

Interventions/setting

All studies reported on individual or group interventions provided in outpatient settings. Four studies involved psychosocial interventions delivered in a group format according to manualised treatment programmes. In three studies (Barbic, Krupa, & Armstrong, 2009; Fardig, Lewander, Melin, Folke, & Fredriksson, 2011; Salyers et al., 2014), the treatment manuals had been published previously. The Illness Management and Recovery (IMR) programme was evaluated in two studies (Fardig et al., 2011; Salyers et al., 2014), the Recovery Workbook (RW) programme in another study (Barbic et al., 2009) and the Pathways to Recovery (PtR) programme in the study that used a non-published manual (Green, Janoff, Yarborough, & Paulson, 2013). Group sizes ranged from *n*=3 to 9 participants. All group interventions were delivered during weekly sessions, with durations ranging from 1 to 2 hours. Number of group sessions offered across studies ranged from 10 to 40 sessions. Both IMR programmes were completed over 9 months, whereas the RW and PtR programmes were delivered over periods of 12 weeks and 10 weeks, respectively. All group interventions were co-facilitated. In two studies (Barbic et al., 2009; Green et al., 2013), at least one of the group facilitators was a member of the research team, and in one of these studies (Green et al., 2013) a service user was a co-facilitator. In Fardig et al. (2011), co-facilitators were clinicians recruited for the study due to their interest in IMR, and in Salyers et al. (2014) the co-facilitators were psychologists or masters-level clinician alongside doctoral psychology students.

Group interventions offered a mix of psychoeducation, group discussion and practice of new skills. All group interventions involved setting personal goals, learning how to manage stress and building social support. The RW and IMR studies also supported

participants to develop a greater understanding of their mental health condition and working with the mental health system, while the IMR studies expanded their focus to the effective use of anti-psychotic medications, coping with symptoms and relapse prevention. Most group interventions used homework assignments to enhance learning. Participants in the IMR and RW groups received treatment as usual (TAU) in addition to the group interventions.

Six interventions were delivered in an individual format with a range of 10 to 30 sessions offered across studies. Sessions typically lasted 1 hour per week, with the intervention period ranging from 4 to 12 months. Two studies evaluated the effects of individual cognitive therapy (CT) on personal recovery. In both studies, CT interventions were delivered via a manualised approach (Morrison, 2001). Therapists delivering interventions had prior training in CT, with trial specific training, and had regular supervision throughout the trials. Therapists' fidelity to protocol was evaluated in one study (Morrison et al., 2014) through audio recording of sessions and independent rating using the Cognitive Therapy Scale-Revised (CTS-R). One study evaluated an Experience-Focused Counselling (EFC) intervention whereby mental health practitioners were trained to work collaboratively with participants to develop an understanding of voice hearing experiences in the context of life experiences. Another study examined the effects of an individual Guided Self-Determination for Schizophrenia (GSD-SZ) intervention which involved mental health practitioners being trained to help participants develop skills in shared decision making and problem solving.

Comparators

Eight studies compared intervention effects to control conditions where participants received TAU. TAU was offered on its own in most studies except for the two CT studies where it was supplemented by regular monitoring. The authors argued that TAU plus monitoring was superior to TAU alone because participants received benefits from a supportive and non-judgemental therapeutic relationship and signposting to appropriate services if necessary. There was variance across and within studies on components of TAU. In one study (Morrison et al., 2014) participants referred from Early Intervention (EI) services were likely to have regular contact with a care coordinator and access to other psychosocial interventions such as family work, whilst participants from other community services were likely to have less consistent care coordinator contact and limited access to other mental health professionals. Other studies indicated that TAU could involve medication, cognitive behavioural therapy (CBT), psychoeducation and social skills training. Only one study evaluated intervention effects against an active treatment control group. This involved control participants receiving a problem solving intervention with the same format, number, frequency and duration of sessions as the experimental group. The final study used a delayed-intervention control group.

Outcome measurement

Primary outcome

Personal recovery was included as a primary outcome in three studies (Green et al., 2013; Schnackenberg et al., 2016; Slade et al., 2015), a secondary outcome in a further three studies (Jorgensen et al., 2015; Morrison et al., 2016; Morrison et al., 2014) and

not stated as a primary or secondary outcome in the remaining four studies. No studies indicated measurement of personal recovery as a mediating or moderating variable.

Six studies measured participants' perception of recovery using RAS. Five studies analysed RAS total scores, while one study (Huguelet et al., 2011) reported only individual scores yielded from each of the five RAS domains: *personal confidence and hope*, *willingness to ask for help*, *reliance on others*, *not dominated by symptoms*, and *goal and success orientation*. Of the five studies that used RAS total scores, all but one (Fardig et al., 2011) analysed and reported the individual domain scores too. The remaining four studies used the QPR in their outcome battery.

Finally, two studies measured participants own judgements of empowerment using the Mental Health Confidence Scale (MHCS; Carpinello et al., 2000) and the Empowerment Scale (EmS; Rogers et al., 1997).

Secondary outcomes

Eight studies measured change in psychiatric symptoms over time. All measures were interviewer-rated with assessment of recent symptoms by semi-structured interview. The Positive and Negative Syndrome Scale (PANSS; Kay et al., 1987) was used in the majority of studies (*n=5*). Other studies used a modified version of the Psychosis Evaluation Tool for Common Use by Caregivers (PECC; De Hert et al., 2002) (*n=1*), the Brief Psychiatric Rating Scale (BPRS; Overall & Gorham, 1962) (*n=1*), and the Brief Psychiatric Rating Scale – Expanded Version (BPRS-E; Lukoff et al., 1986) (*n=1*). Only two studies (Morrison et al., 2016; Morrison et al., 2014) measured depression and anxiety. Three studies measured interviewer-rated changes in general functioning

using the Global Assessment of Functioning Scale (GAF; Endicott et al., 1976), while one study measured social functioning using the interviewer-rated Personal and Social Performance Scale (PSP; Morosini et al., 2000). Six studies measured changes in self-reported quality of life using a range of measures: The Quality of Life Index, General Version (QOLI; Ferrans & Powers, 1985) (*n=1*); the Manchester Short Assessment of Quality of Life (MANSA; Priebe et al., 1999) (*n=2*); the World Health Organisation Quality of Life Instrument (WHOQOL-BREF; The WHOQOL Group, 1998) (*n=1*); and the Wisconsin Quality of Life Index (W-QLI; Becker et al., 1993) (*n=1*). A further study used the interviewer-rated Quality of Life Scale (QLS; Bilker et al., 2003).

Follow-up

Nine studies examined the effectiveness of the psychosocial intervention by measuring outcomes immediately following its completion (i.e. post-intervention). Post-intervention time points across studies ranged from three to 12 months. Six studies investigated whether post-intervention effects had been sustained by measuring outcomes at follow-up points ranging from three to 12 months after post-intervention. One study, in which the intervention was a spiritual assessment followed by supervision of the psychiatrist providing clinical care to the participant, did not measure outcomes immediately following completion of the assessment, but after a period of three months and there was no further follow-up.

Risk of bias

Risk of bias ratings for individual studies are shown in Table 2. Ratings recorded by the primary author (HL) can be found in Appendix 4. The majority of studies (*n*=6) described adequate methods of randomisation to treatment groups. Not all studies described methods to ensure allocation was concealed to study personnel, so it was unclear if these studies were affected by selection bias. Performance bias may have influenced an overestimation of treatment effects in all studies because, even when studies followed adequate procedures to conceal group allocation at the point of randomisation, the nature of participating in a psychosocial intervention revealed allocation to both the intervention providers and participants. Although outcomes were assessed by blind raters in the majority of studies (*n*=6), only two studies reported methods to prevent blind breaks and procedures for remedial action when they occurred (Morrison et al., 2016; Morrison et al., 2014). There was a high risk of detection bias in four studies where treatment allocation was known to raters (Jorgensen et al., 2015; Schnackenberg et al., 2016) (Jorgensen et al., 2015; Schnackenberg et al., 2016; Slade et al., 2015) or blinding of raters was not reported (Green et al., 2013). There was a threat to attrition bias in four studies where the loss to follow-up rate exceeded 25% (Morrison et al., 2014; Salyers et al., 2014; Schnackenberg et al., 2016; Slade et al., 2015), and it was unclear if this was the case for two studies where missing data and attrition was not explicitly reported. The majority of studies (*n*=6), reported using intention-to-treat analyses. Finally, there was a high risk of selective reporting bias in two studies (Green et al., 2013; Schnackenberg et al., 2016) where published reports omitted data on some of the pre-specified outcomes, and the effect of selective reporting on results was unclear in a further five

studies (Barbic et al., 2009; Fardig et al., 2011; Huguelet et al., 2011; Morrison et al., 2016; Salyers et al., 2014) where there was no pre-published protocol.

Table 2. Risk of bias ratings across individual studies

Study	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Barbic et al. 2009	Unclear	Unclear	High	Unclear	Unclear	Unclear	Unclear
Fardig et al. 2011	Low	Unclear	High	Unclear	Low	Unclear	Unclear
Huguelet et al. 2011	Low	Unclear	High	Unclear	Unclear	Unclear	Unclear
Green et al. 2013	Unclear	Unclear	High	High	Unclear	High	Unclear
Morrison et al. 2014	Low	Low	High	Low	High	Low	Unclear
Salyers et al. 2014	Unclear	Unclear	Unclear	Unclear	High	Unclear	Unclear
Jorgensen et al. 2015	Low	Low	High	High	Low	Low	Unclear
Slade et al. 2015	Low	Low	High	High	High	Low	Unclear
Morrison et al. 2016	Low	Low	High	Low	Low	Unclear	Unclear
Schnackenberg et al. 2016	Unclear	Unclear	High	High	High	High	Unclear

Effectiveness of interventions

Table 3 details the pre-to post-intervention and pre-to follow-up effect sizes for each available outcome of interest to the review, alongside a summary of key findings from each study, including between-group differences over time as reported by study authors.

Primary outcomes

Personal recovery

Effect sizes representing change in personal recovery total scores within groups from pre-to post-intervention were reported for six studies (Barbic et al., 2009; Fardig et al., 2011; Morrison et al., 2016; Morrison et al., 2014; Salyers et al., 2014; Slade et al., 2015). Intervention participants demonstrated improvement in overall personal recovery from pre-to post intervention in all but one study (Salyers et al., 2014). Receipt of individualised, manualised, psychosis-specific CT was associated with the greatest improvement in personal recovery. In the standard CT for psychosis study, there was moderate improvement (*d*=0.51) at post-intervention, large improvement (*d*=1.10) at 6 month follow-up, with a large effect sustained (*d*=0.81) at nine-month follow-up (Morrison et al., 2014). When CT was adapted to address high levels of internalised stigma, there was a large effect of the intervention at post-intervention (*d*=1.33) and three months later (*d*=1.15). Control participants in this study, who received TAU plus monitoring, did not show any improvement in overall personal recovery post-intervention and a small improvement three months later.

A further three studies showed small pre-to post-intervention improvements in overall personal recovery (Barbic et al., 2009; Fardig et al., 2011; Slade et al., 2015). Control

participants in these studies (REFOCUS and IMR) also showed small improvements, while those in the RW study had a small deterioration in post-intervention personal recovery scores. It was only possible to assess the longevity of personal recovery outcomes in the IMR study because the others did not have further follow-ups. When outcomes were assessed a year later (after post-intervention), there was a moderate improvement for the IMR group while the improvement had become almost negligible for the TAU controls. Interestingly, the second IMR group study (Salyers et al., 2014) failed to demonstrate any effect on personal recovery total scores for the intervention group at post-intervention, or at a follow-up assessment nine months later. On the other hand, control participants who took part in a problem solving group showed improvement of a small magnitude which was maintained at nine-month follow-up.

Three studies reported significant differences between intervention and TAU control groups in overall personal recovery (Barbic et al., 2009; Green et al., 2013; Morrison et al., 2016). In particular, the RW and PtR groups led to greater judgements of personal recovery over time than TAU, while individualised CT for internalised stigma led to improvements in favour of the CT group at the four-month post-intervention but not at a follow-up 3 months later. A fourth study (Huguelet et al., 2011) found a significant difference between groups in the domain 'willingness to ask for help', with participants who had received a spiritual assessment more willing to ask for help three months later than TAU controls.

Empowerment

Changes in participants' perceptions of empowerment were measured in two studies. The 12-week recovery workbook group led to a large improvement (*d*=-4.63) in

empowerment, while TAU controls only had a small improvement (*d*=-0.27). The one-year REFOCUS intervention led to a small increase in empowerment (*d*=0.13), with a slight increase (*d*=0.06) for TAU controls. Sustainability of effects could not be evaluated as neither study included a follow-up. Only the RW study found a significant difference between groups over time with group participants reporting a significantly greater perception of empowerment than TAU participants.

Secondary outcomes

Psychiatric symptoms

Within-group effect sizes were calculated for six of the eight studies that measured severity of psychiatric symptoms, while two studies did not report raw scores to allow for calculation. Five studies found that psychosocial interventions reduced total psychiatric symptom severity scores at post-intervention, while one study found that total symptoms worsened three months after a spiritual assessment had been carried out. Individual CT delivered over nine months led to a large reduction (*d*=-0.86) in psychiatric symptom severity at post-intervention. Moreover, the large effect was sustained at further follow-ups of six and nine months. In comparison, control participants who received TAU plus monitoring had a moderate improvement (*d*=-0.75) at post-intervention, which reduced to small improvements at three, six, and nine-month follow-ups. Individual EFC delivered over 11 months also resulted in a large improvement (*d*=-0.91) in psychiatric symptom severity for the intervention group, whereas there was slight deterioration for TAU controls. Another large improvement (*d*=-0.88) was found for an IMR group, which lowered to a moderate effect (*d*=-0.73) one year later (Fardig et al., 2011). TAU participants in this study demonstrated only a small improvement (*d*=-0.20) in psychiatric symptom severity at post-intervention,

followed by a small deterioration (*d*=0.13) one year later. Small improvements were found for the other IMR group, which converted to a large improvement (*d*=-0.80) at a follow-up 9 months later (Salyers et al., 2014). In comparison, control participants who took part in a problem solving group showed moderate improvement (*d*=-0.63) in psychiatric symptoms at post-intervention; an outcome that was maintained at follow-up. In the team-level REFOCUS intervention, there was a small improvement (*d*=-0.24) in psychiatric symptom severity for the intervention group at post-intervention, and there was also a small improvement to a lesser degree (*d*=-0.06) for the TAU controls. Participants who took part in a spiritual assessment had a small deterioration (*d*=0.13) in psychiatric symptom severity at 3 month follow-up, and this was also the case for the TAU controls (*d*=0.25).

Four studies reported significant group differences regarding severity of psychiatric symptoms. Specifically, participants who received individual CT for psychosis (Morrison et al., 2014), individual GSD-SZ (Jorgensen et al., 2015), and one IMR group (Fardig et al., 2011) were found to have significantly reduced total severity scores compared to TAU at post-intervention and further follow-ups ranging from 6 to 12 months. Individual EFC led to a significant difference between groups in favour of the intervention only for the psychosis subscale. Although there were no between-group differences in the second IMR study, both the intervention group and the problem solving control group showed significant improvement (*d*>0.5) in psychiatric symptoms over time (Salyers et al., 2014).

Depression and anxiety

Two studies examined the effects of individual CT on severity of depression and anxiety symptoms. Intervention groups reported moderate to large improvements in depression severity from baseline to post-intervention and follow-up. Those who received TAU had small to moderate improvements over these time points. Regarding symptoms of social anxiety, small to moderate improvements were found for intervention groups in both studies at post-intervention and follow-up. TAU groups in both studies had small improvements at post-intervention, which was maintained after 3 months for TAU participants in the CT for internalised stigma trial, but not for TAU participants in the standard CT trial.

When group comparisons were considered, only CT modified to address internalised stigma led to a significant difference in depression scores in favour of the intervention over TAU at post-intervention; an effect that was lost by a 3-month follow-up. Neither study found significant differences between groups in levels of social anxiety.

Functioning

Four studies measured changes in functioning and it was possible to calculate within-group effect sizes for all but one study (Jorgensen et al., 2015). CT for psychosis resulted in moderate improvement (d=0.54) in personal and social functioning at post-intervention, while TAU had small to moderate improvement (d=0.43). Moderate improvements were maintained for CT participants at further follow-ups of 3, 6 and 9 months, while control participants had only small improvements at these time points. The REFOCUS intervention led to a small improvement in global functioning, while there was no change for TAU controls. Finally, a spiritual assessment had no effect on

global functioning when it was assessed 3 months later, while those who received TAU had a slight deterioration in global functioning.

Three studies reported significant group differences concerning functioning. Individual CT resulted in significantly improved personal and social functioning compared to TAU, which was sustained at 9-month follow-up. The REFOCUS intervention led to significantly better global functioning than TAU at post-intervention. Finally, the GSD-SZ participants showed significantly better functioning over time than TAU on the GAF symptom subscale, but not the function subscale.

Quality of life

Within-group effect sizes for five of the six studies that measured quality of life are displayed in Table 2. Small pre-post improvements were found for the RW, REFOCUS intervention and both IMR trials. In addition, the spiritual assessment resulted in a small improvement only on the social domain of quality of life, but this was also the case for TAU controls. An active PS control group fared better on quality of life at post-intervention than the IMR group with mean scores approaching the moderate range (d=-0.48). Both IMR and PS control groups maintained small improvements at follow-up 9 months later. The other IMR trial found that small treatment effects were not maintained one year later (Fardig et al., 2011).

No studies found significant group differences on quality of life. When IMR was evaluated against a problem solving intervention both groups improved significantly over time in quality of life (d=0.4) (Salyers et al., 2014).

Adverse events

The published reports for four studies failed to mention the occurrence or absence of adverse events during the trials (Barbic et al., 2009; Fardig et al., 2011; Green et al., 2013; Salyers et al., 2014). For the other six studies, adverse events affected 1 to 10% of participants, including compulsory and voluntary admissions to hospital, overdose attempts and deaths. In most cases these events were deemed not to be linked to trial participation, but the reporting was unclear in some studies (Table 3).

Table 3. Summary of outcomes

Study	Outcome measures relevant to review	Treatment condition	N at time point (months from baseline)	Pre mean (SD)	Post mean (SD)	Follow-up mean (SD)	Pre-post effect size (Cohen's *d*)	Pre-follow-up effect size (Cohen's *d*)	Analysis	Summary of key findings
Barbic et al. (2009)	Personal recovery: RAS Quality of life: QOLI Empowerment: EmS	RW group + TAU	**Baseline** n=16 **3 months** NR	**Baseline** RAS Total: 163.75 (22.60) RAS Hope: 34.43 (6.26) RAS Help: 12.31 (1.74) RAS Reliance: 19.81 (3.69) RAS Symptoms: 17.00 (2.06) RAS Success: 11.50 (2.03) QOLI: 20.34 (5.01) EmS: 55.93 (6.91)	**3 months** RAS Total: 168.81 (20.11) RAS Hope: 37.13 (5.51) RAS Help: 12.00 (2.33) RAS Reliance: 21.31 (2.91) RAS Symptoms: 17.18 (1.79) RAS Success: 11.75 (2.11) QOLI: 21.60 (3.35) EmS: 14.93 (10.43)	N/A	RAS Total: 0.24 RAS Hope: 0.46 RAS Help: -0.15 RAS Reliance: 0.45 RAS Symptoms: 0.09 RAS Success: 0.12 QOLI: 0.30 EmS: -4.63	N/A	Analyses for all variables were ITT. Time x team x group repeated measures ANOVA. Drop-out not reported. Methods for missing data not described.	RAS: RW group showed significantly greater improvement on total personal recovery scores, as well as the 'personal confidence and hope' and 'goal and success orientation' subscale scores, than the TAU group at post-intervention. EmS: RW group showed significantly greater improvement in empowerment scores than the TAU group at post-intervention. QOLI: no significant effect between group and time on quality of life scores. Adverse events not reported.
		TAU alone	**Baseline** n=17 **3 months** NR	**Baseline** RAS Total: 156.41 (14.22) RAS Hope: 33.17 (4.71) RAS Help: 11.47 (2.74) RAS Reliance: 19.88 (3.14) RAS Symptoms: 5.47 (2.03) RAS Success: 10.41 (1.91) QOLI:	**3 months** RAS Total: 149.11 (22.09) RAS Hope: 31.82 (7.92) RAS Help: 11.11 (1.73) RAS Reliance: 18.35 (4.74) RAS Symptoms: 14.76 (2.61) RAS Success: 9.65 (2.62) QOLI:	N/A	RAS Total: -0.39 RAS Hope: -0.21 RAS Help: -0.16 RAS Reliance: -0.38 RAS Symptoms: 3.97 RAS Success: -0.33 QOLI:	N/A		

				20.70 (4.13) EmS: 63.88 (6.91)	22.27 (4.91) EmS: 61.96 (7.33)		0.35 EmS: -0.27			
Fardig et al. (2011)	Personal recovery: RAS Psychiatric symptoms: PECC Quality of life: MANSA	IMR group + TAU	**Baseline** n=21 **9 months** n=21 **21 months** n=19	**Baseline** RAS Total: 3.65 (0.45) PECC Total: 48.14 (14.08) MANSA: 54.70 (9.11)	**9 months** RAS Total: 3.82 (0.46) PECC Total: 37.25 (10.32) MANSA: 55.70 (7.60)	**21 months** RAS Total: 3.89 (0.32) PECC Total: 37.68 (14.49) MANSA: 53.94 (7.68)	**9 months** RAS Total: 0.37 PECC Total: -0.88 MANSA: 0.12	**21 months** RAS Total: 0.61 PECC Total: -0.73 MANSA: -0.09	Did not state whether ITT analyses used. Relative change in outcomes evaluated at post-intervention and follow-up using a linear repeated-measures mixed model with baseline data entered as random covariates.	RAS: No significant differences were found for either group between assessment points. PECC: At both 9 and 21 months, compared with the TAU group, the IMR group had significantly greater reduction in total PECC scores and subscale scores for positive symptoms, negative symptoms, depression and anxiety, and insight. No significant difference on mania subscale. MANSA: No significant differences were found for either group in quality of life between assessment points. Adverse events not reported.
		TAU alone	**Baseline** n=20 **9 months** n=20 **21 months** n=19	**Baseline** RAS Total: 3.85 (0.60) PECC Total: 53.90 (15.61) MANSA: 52.90 (9.92)	**9 months** RAS Total: 3.93 (0.52) PECC Total: 50.90 (14.67) MANSA: 52.90 (10.02)	**21 months** RAS Total: 3.87 (0.47) PECC Total: 55.68 (11.26) MANSA: 49.53 (10.05)	**9 months** RAS Total: 0.14 PECC Total: -0.20 MANSA: 0	**21 months** RAS Total: 0.04 PECC Total: 0.13 MANSA: -0.34		

Huguelet et al. (2011)	Personal recovery: RAS Psychiatric symptoms: PANSS Functioning: GAF Quality of Life: WHOQOL-BREF	Individual spiritual assessment + TAU	**Baseline** n=42 **3 months** n=40	**Baseline** RAS Total: NR RAS Hope: 31 (6) RAS Help: 12 (2) RAS Reliance: 15 (3) RAS Symptoms: 10 (3) RAS Success: 18 (4) PANSS Total: 58 (15) GAF: 51 (9) WHOQOL-BREF *Physical:* 61 (17) *Psychological:* 61 (15) *Social:* 51 (24) *Environmental*: 64 (14)	**N/A**	**3 months** RAS Total: NR RAS Hope: 31 (5) RAS Help: 12 (1) RAS Reliance: 14 (3) RAS Symptoms: 9 (3) RAS Success: 19 (4) PANSS Total: 60 (16) GAF: 51 (9) WHOQOL-BREF *Physical:* 58 (16) *Psychological*: 58 (18) *Social*: 54 (20) *Environmental*: 62 (17)	**N/A**	**3 months** RAS Total: N/A RAS Hope: 0 RAS Help: 0 RAS Reliance: -0.33 RAS Symptoms: -0.33 RAS Success: 0.25 PANSS Total: 0.13 GAF: 0 WHOQOL-BREF *Physical:* -0.18 *Psychological:* -0.18 *Social:* 0.14 *Environmental:* -0.13	Did not state whether ITT analyses used. Linear mixed models with maximum likelihood estimation were used to analyse between-group differences in outcome measures, with treatment time as a fixed effect and the individual a random effect.	RAS: Scores on the 'willingness to ask for help' subscale were significantly higher in the spiritual assessment group than the TAU alone group at 3-month follow-up, indicating that participants who received the spiritual assessment were more willing to ask for help. No other significant differences were found across groups at three month follow-up. Adverse events: 1 participant in the spiritual assessment group was hospitalised and lost to follow-up. No further information given.
		TAU alone	**Baseline** n=42 **3 months** n=38	**Baseline** RAS Total: NR RAS Hope: 33 (5) RAS Help: 12 (2) RAS Reliance: 15 (3) RAS Symptoms: 9 (3) RAS Success: 19 (4) PANSS Total: 56 (15) GAF: 52 (11)	**N/A**	**3 months** RAS Total: NR RAS Hope: 32 (5) RAS Help: 11 (2) RAS Reliance: 14 (3) RAS Symptoms: 9 (3) RAS Success: 19 (4) PANSS Total: 60 (17) GAF: 51 (10)	**N/A**	**3 months** RAS Total: NR RAS Hope: -0.2 RAS Help: -0.5 RAS Reliance: -0.33 RAS Symptoms: 0 RAS Success: 0 PANSS Total: 0.25 GAF: -0.09		

				WHOQOL-BREF *Physical*: 61 (11) *Psychological*: 59 (16) *Social*: 53 (21) *Environmental*: 62 (15)		WHOQOL-BREF *Physical*: 60 (11) *Psychological*: 58 (14) *Social*: 55 (16) *Environmental*: 62 (10)		WHOQOL-BREF *Physical*: -0.09 *Psychological*: -0.07 *Social*: 0.11 *Environmenta*l: 0		
Green et al. (2013)	Personal recovery: RAS Psychiatric symptoms: CSI Quality of life: W-QLI	PtR group	**Baseline** Unclear whole sample, n=30 **3 months** Unclear whole sample, n=28	NR	NR	N/A	N/A	N/A	Did not state whether ITT analysis was used. Between-group differences analysed by ANCOVA adjusting for baseline values. Methods for missing data not described.	RAS: Significant between-group differences found for overall personal recovery and 'not dominated by symptoms' subscale scores, with the PtR group demonstrating significantly greater improvement than the waitlist control group at 3 months. W-QLI: PtR group had significantly greater improvement on the W-QLI general life satisfaction scale than the waitlist control group by 3 months. CSI: No significant between-group differences were found for
		Delayed-intervention waitlist control	**Baseline** Unclear whole sample, n=30 **3 months** Unclear whole sample, n=28	NR	NR	N/A	N/A	N/A		

										psychiatric symptoms. Adverse events not reported.
Morrison et al. (2014)	Personal recovery: QPR Psychiatric symptoms: PANSS Depression: BDI-PC Anxiety: SIAS Functioning: PSP	Individual CT + TAU + monitoring	**Baseline** n=37 **9 months** QPR Total: n=25 PANSS Total: n=22 BDI-PC: n=26 SIAS: n=24 PSP: n=23 **12 months** *(possible n=34)* QPR Total: n=16 PANSS Total: n=18 BDI-PC: n=18 SIAS: n=15 PSP, n=19 **15 months**	**Baseline** QPR Total: 29.35 (11.15) PANSS Total: 70.24 (13.75) BDI-PC: 10.54 (5.21) SIAS: 40.43 (19.76) PSP: 56.84 (16.45)	**9 months** QPR Total: 35.12 (11.76) PANSS Total: 57.95 (14.99) BDI-PC: 6.35 (5.93) SIAS: 31.71 (16.34) PSP: 65.00 (12.75)	**12 months** QPR Total: 34.00 (16.41) PANSS Total: 58.56 (18.85) BDI-PC: 7.44 (6.34) SIAS: 30.00 (22.38) PSP: 65.37 (17.63) **15 months** QPR Total: 41.63 (11.22) PANSS Total: 54.68 (14.61) BDI-PC: 4.50 (4.05) SIAS: 28.59 (18.21) PSP: 65.84 (18.22) **18 months** QPR Total: 39.50 (15.46) PANSS Total: 56.47 (18.22) BDI-PC: 5.50 (5.63) SIAS: 31.31 (20.87) PSP: 64.74 (20.24)	**9 months** QPR Total: 0.51 PANSS Total: -0.86 BDI-PC: -0.76 SIAS: -0.47 PSP: 0.54	**12 months** QPR Total: 0.36 PANSS Total: -0.75 BDI-PC: -0.55 SIAS: -0.51 PSP: 0.51 **15 months** QPR Total: 1.10 PANSS Total: -1.11 BDI-PC: -1.23 SIAS: -0.61 PSP: 0.53 **18 months** QPR Total: 0.81 PANSS Total: -0.90 BDI-PC: -0.94 SIAS: -0.45 PSP: 0.44	Primary analysis was by ITT. Data analysed by random effects regression models, with covariates of site, sex, age, and baseline value of the outcome being measured. Missing-at-random assumption used to account for missing data.	QPR, BDI-PC & SIAS: No significant group effects were found on measures of personal recovery, depression or anxiety. PANSS: Total scores were consistently less in the CT group compared to the TAU group (-6.52, 95% CI -10.79 to -2.25). The estimated between-group effect size (unstandardised) equated to Cohen's d=0.46. Similar significant effects of the CT intervention were found on positive symptoms (-2.22, -4.00 to -0.44) and general symptoms (-3.63, -5.99 to -1.27). There was no significant effect of CT on negative symptoms.

			(possible n=30) QPR Total: n=16 PANSS Total: n=19 BDI-PC: n=16 SIAS: n=17 PSP, n=19 **18 months** *(possible n=26)* QPR Total: n=16 PANSS Total: n=17 BDI-PC: n=16 SIAS: n=16 PSP: n=19							PSP: A significant effect of group in favour of CT was found, with the intervention group scoring significantly higher (higher scores are preferable) on the social functioning measure than the TAU group (5.47, 0.18 to 10.77). Treatment effects did not vary with time of follow-up (no significant treatment by time interactions). Adverse events: Eight serious adverse events reported. Two adverse events in the CT group: following the intervention one participant attempted overdose and another presented a risk to others. Six adverse events in the TAU control group: 2 deaths which were deemed unrelated to mental health or the trial; 3 compulsory admissions to
		TAU + monitoring	**Baseline** n=37 **9 months** QPR total: n=21 PANSS Total: n=23 BDI-PC: n=21	**Baseline** QPR Total: 28.76 (11.78) PANSS Total: 73.27 (13.42) BDI-PC: 9.41 (4.03) SIAS: 45.15 (15.19) PSP: 50.03 (16.19)	**9 months** QPR Total: 32.10 (8.80) PANSS Total: 63.26 (13.21) BDI-PC: 7.14 (3.35) SIAS: 40.48 (13.88) PSP: 56.74 (15.02)	**12 months** QPR Total: 31.87 (9.64) PANSS Total: 68.33 (15.03) BDI-PC: 7.00 (3.54) SIAS: 41.86 (14.87) PSP: 52.95 (15.50)	**9 months** QPR Total: 0.31 PANSS Total: -0.75 BDI-PC: -0.60 SIAS: -0.32 PSP: 0.43	**12 months** QPR Total: 0.28 PANSS Total: -0.35 BDI-PC: -0.62 SIAS: -0.22 PSP: 0.18		

			SIAS: n=21 PSP: n=23 **12 months** *(possible n=34)* QPR Total: n=15 PANSS Total: n=21 BDI-PC: n=17 SIAS: n=14 PSP: n=21 **15 months** *(possible n=30)* QPR Total: n=13 PANSS Total: n=16 BDI-PC: n=13 SIAS: n=11 PSP: n=15 **18 months** *(possible n=25)*			**15 months** QPR Total: 29.69 (9.71) PANSS Total: 69.94 (14.35) BDI-PC: 7.38 (4.29) SIAS: 45.27 (16.44) PSP: 53.53 (18.75) **18 months** QPR Total: 29.38 (8.76) PANSS Total: 71.24 (20.35) BDI-PC: 7.38 (5.16) SIAS: 44.06 (18.21) PSP: 55.94 (20.29)		**15 months** QPR Total: 0.08 PANSS Total: -0.24 BDI-PC: -0.50 SIAS: 0.01 PSP: 0.21 **18 months** QPR Total: 0.06 PANSS Total: -0.13 BDI-PC: -0.46 SIAS: -0.07 PSP: 0.34		hospital under the Mental Health Act; and 1 attempted overdose. One voluntary hospital admission lasting 4 days in the follow-up phase for a participant in the intervention group.

			QPR Total: n=16 PANSS Total: n=17 BDI-PC: n=16 SIAS: n=16 PSP: n=18							
Salyers et al. (2014)	Personal recovery: RAS Psychiatric symptoms: PANSS Quality of life: QLS	IMR group + TAU	**Baseline** n=59 **9 months** n=44 **18 months** n=37	**Baseline** RAS Total: 3.1 (0.4) RAS Hope: 3.0 (0.6) PANSS Total: 75.1 (16.1) QLS: 3.1 (1.1)	**9 months** RAS Total: 3.1 (0.4) RAS Hope: 3.0 (0.6) PANSS Total: 68.5 (18.5) QLS: 3.3 (1.1)	**18 months** RAS Total: 3.1 (0.4) RAS Hope: 2.9 (0.6) PANSS Total: 61.9 (17.1) QLS: 3.5 (1.0)	**9 months** RAS Total: 0 RAS Hope: 0 PANSS Total: -0.38 QLS: 0.18	**18 months** RAS Total: 0 RAS Hope: -0.17 PANSS Total: -0.80 QLS: 0.38	ITT analyses used. Mixed effects regression analyses of mean-response profiles, with covariates of site and baseline values of the outcome being measured. Maximum likelihood estimation used to account for missing data.	No significant group effects between the IMR group and problem solving control group on any of the outcome measures. Both groups showed significant improvement over time on measures of psychiatric symptoms (Cohen's d>0.5) and quality of life (Cohen's d=0.4). Adverse events not reported.
		Active control problem solving group + TAU	**Baseline** n=57 **9 months** n=40 **18 months** n=33	**Baseline** RAS Total: 3.0 (0.4) RAS Hope: 2.9 (0.7) PANSS Total: 76.1 (15.3) QLS: 2.8 (1.0)	**9 months** RAS Total: 3.1 (0.4) RAS Hope: 3.0 (0.7) PANSS Total: 66.6 (14.9) QLS: 3.3 (1.1)	**18 months** RAS Total: 3.1 (0.5) RAS Hope: 3.0 (0.7) PANSS Total: 65.3 (19.6) QLS: 3.3 (1.3)	**9 months** RAS Total: 0.25 RAS Hope: 0.14 PANSS Total: -0.63 QLS: 0.48	**18 months** RAS Total: 0.23 RAS Hope: 0.14 PANSS Total: -0.64 QLS: 0.45		
Jorgensen et al. (2015)	Personal recovery: RAS Psychiatric symptoms: PANSS Functioning:	Individual GSD-SZ + TAU	**Baseline** n=50 **6 months** n=47 **12 months** n=45	**Baseline** RAS Total: 147.5 (20.0) RAS Hope: 24.8 (4.2) RAS Help: 9.9 (2.4) RAS Reliance: 14.9 (2.5)	**6 months** NR	**12 months** NR (only change in scores reported)	N/A	N/A	All analyses were ITT. Group-by-time interactions were analysed using linear mixed effects regression analyses and	RAS: No significant difference between groups found on the personal recovery measure. PANSS: Significantly greater improvement in

	GAF			RAS Symptoms: 10.0 (2.4) RAS Success: 18.6 (3.8) PANSS Total: 66.7 (9.8) GAF: 40.8 (3.8)					each individual entered as a random effect. Multiple imputation was applied on missing outcome data with 20 imputations estimated for each missing value.	scores over time observed in the GSD-SZ group than the TAU alone group for total symptom scores (-4.57, 95% CI -8.71 to -0.44), as well as negative symptoms (-1.81, -3.49 to -0.14) cognitive symptoms (-2.43, -3.94 to -0.92), and emotional discomfort (-1.22, -2.32 to -0.13). The GSD-SZ participants experienced a significant increase (i.e. deterioration) on the excitement subscale compared to the TAU participants (0.75, 0.05 to 1.44). GAF: GSD-SZ participants showed significantly greater improvement than the TAU participants on the GAF symptom subscale (2.17, 95% CI 0.37 to 3.98). There were no significant differences between groups on the GAF function subscale.
		TAU alone	**Baseline** n=51 **6 months** n=47 **12 months** n=48	**Baseline** RAS Total: 146.1 (20.0) RAS Hope: 24.2 (4.3) RAS Help: 9.5 (2.4) RAS Reliance: 14.6 (2.8) RAS Symptoms: 9.5 (2.4) RAS Success: 18.7 (3.3) PANSS Total: 65.5 (11.1) GAF: 41.3 (4.3)	**6 months** NR	**12 months** NR (only change in scores reported)	N/A	N/A		

										Adverse events: Reported that 1 participant died, but no further information provided so unclear if this was related to participation in the trial.
Slade et al. (2015)	Personal recovery: QPR Psychiatric symptoms: BPRS Functioning: GAF Quality of life: MANSA Empowerment: MHCS	REFOCUS team level intervention + TAU	**Baseline** n=210 (14 teams) **12 months** n=141 (14 teams)	**Baseline** QPR Total: 38.53 (9.31) QPR Intrapersonal: 43.77 (10.18) QPR Interpersonal: 13.55 (2.43) BPRS Total: 33.63 (10.13) GAF: 64.66 (13.88) MANSA: 4.75 (0.97) MHCS: 65.23 (14.40)	**12 months** QPR Total: 40.89 (9.90) QPR Intrapersonal: 46.04 (11.50) QPR Interpersonal: 13.81 (2.70) BPRS Total: 31.60 (10.40) GAF: 67.69 (13.10) MANSA: 4.80 (0.95) MHCS: 67.20 (15.50)	**N/A**	**12 months** QPR Total: 0.25 QPR Intrapersonal: 0.21 QPR Interpersonal: 0.10 BPRS Total: -0.24 GAF: 0.22 MANSA: 0.05 MHCS: 0.13	N/A	Analyses of imputed data were ITT. Differences between groups on the outcome measures were analysed by random effects regression analyses, with adjustment for baseline scores. Missing data were estimated with multiple (50) imputations by chained equation to account for clustering at team level. Maximum likelihood estimation used.	QPR, BPRS, MANSA, & MHCS: No significant differences between the REFOCUS and TAU groups at post-intervention. GAF: REFOCUS group had significantly greater improvement than TAU group on the functioning measure (5.90, 95% CI 2.61 to 9.18), and the effect remained significant following an adjustment for covariates (5.32, 95% CI 2.03 to 8.61). Adverse events: 3 deaths in each group were reported, but none were deemed
		TAU alone	**Baseline** n=193 (13 teams) **12 months** n= 134 (13 teams)	**Baseline** QPR Total: 38.97 (9.10) QPR Intrapersonal: 43.95 (10.10) QPR Interpersonal: 12.94 (2.67) BPRS Total: 31.90 (9.17) GAF:	**12 months** QPR Total: 39.96 (10.20) QPR Intrapersonal: 45.30 (11.30) QPR Interpersonal: 13.46 (2.60) BPRS Total: 31.27 (10.10) GAF:	**N/A**	**12 months** QPR Total: 0.10 QPR Intrapersonal: 0.13 QPR Interpersonal: 0.20 BPRS Total: -0.06 GAF:	N/A		

				64.15 (14.84) MANSA: 4.60 (0.88) MHCS: 66.38 (14.63)	64.15 (14.80) MANSA: 4.74 (0.92) MHCS: 67.26 (13.90)		0 MANSA: 0.16 MHCS: 0.06			to be due to the intervention.
Morrison et al. (2016)	Personal recovery: QPR Depression: BDI-7 Anxiety: SIAS	Individual CT for internalised stigma + TAU + monitoring	**Baseline** n=15 **4 months** n=13 **7 months** n=14	**Baseline** QPR Total: 27.50 (9.12) BDI-7: 10.50 (4.16) SIAS: 48.94 (16.56)	**4 months** QPR Total: 38.71 (7.55) BDI-7: 6.33 (4.21) SIAS: 39.58 (19.32)	**7 months** QPR Total: 39.17 (11.22) BDI-7: 6.83 (4.57) SIAS: 37.00 (19.26)	**4 months** QPR Total: 1.33 BDI-7: -1.00 SIAS: -0.52	**7 months** QPR Total: 1.15 BDI-7: -0.84 SIAS: -0.67	Primary analysis was ITT. ANCOVA with summed scores as dependent variables and the baseline value of the relevant outcome measure as a covariate. End of treatment and FU data analysed separately on the assumption data Missing at Random.	A power calculation was not conducted because this was intended as a pilot RCT to examine acceptability and feasibility of the intervention. QPR: CT significantly improved personal recovery scores at post-intervention (Mean=38.71, SD=7.55), compared to TAU (Mean=25.75, SD=14.59) (F=12.84, p=0.002, d=1.10). There were no significant differences between groups at the 7 month follow-up. BDI-7: CT significantly improved depression scores at post-intervention (Mean=6.33, SD=4.21), compared to TAU (Mean=9.15, SD=5.21) (F=4.39,
		TAU + monitoring	**Baseline** n=14 **4 months** n=13 **7 months** n=13	**Baseline** QPR Total: 26.31 (14.43) BDI-7: 9.57 (6.56) SIAS: 51.50 (16.22)	**4 months** QPR Total: 25.75 (14.59) BDI-7: 9.15 (5.21) SIAS: 48.77 (17.82)	**7 months** QPR Total: 31.58 (14.41) BDI-7: 6.92 (5.24) SIAS: 46.91 (17.83)	**4 months** QPR Total: -0.04 BDI-7: -0.07 SIAS: -0.16	**7 months** QPR Total: 0.37 BDI-7: -0.44 SIAS: -0.27		

										p=0.048, d=0.59). There were no significant differences between groups at the 7 month follow-up. SIAS: No significant improvement observed in anxiety scores at post-intervention or follow-up. Adverse events: One participant from each group had a voluntary admission to hospital over the course of the trial, and a second participant in the control group attempted overdose and was subsequently hospitalised on a voluntary admission. None of these events were deemed to be related to participation in the trial.
Schnackenberg et al. (2016)	Personal recovery: QPR Psychiatric symptoms:	EFC + TAU	**Baseline** n=12 **11 months** n=7	**Baseline** QPR: NR BPRS-E Total: 61.86 (15.08)	**11 months** QPR: NR BPRSE-Total: 49.29 (12.31)	**N/A**	**11 months** QPR: Raw scores NR BPRS-E Total: -0.91	N/A	Not ITT, complete cases analysis. Group x time repeated measures ANOVA.	QPR: No significant time x group interaction effect for personal recovery over time. Non-significant (data not

	BPRS-E	TAU alone	**Baseline** n=10 **11 months** n=5	**Baseline** QPR: NR BPRS-E Total: 56.20 (16.16)	**11 months** QPR: NR BPRSE-Total: 56.60 (12.76)	**N/A**	**11 months** QPR: Raw scores NR BPRS-E Total: 0.03	N/A	Methods for missing data not described.	published) trend for improved intrapersonal recovery scores in EFC group compared to TAU over time. BPRS-E: No significant time x group interaction effect for total psychiatric symptoms, only for the BPRS-E psychosis subscale where EFC participants showed significantly greater improvement in symptom severity than TAU. Adverse events: Not clearly reported for whole sample. Reported that no EFC group participant left the study or relapsed as a result of the intervention.

Note: ANCOVA, Analysis of covariance; ANOVA, analysis of variance; BDI-7, Beck Depression Inventory for Primary Care; BDI-PC, Beck Depression Inventory for Primary Care; BPRS, Brief Psychiatric Rating Scale; BPRS-E, Brief Psychiatric Rating Scale – Expanded; CI, Confidence interval; CSI, Colorado Symptom Inventory; CT, Cognitive Therapy; EFC, Experience-Focused Counselling; EmS, Empowerment Scale; FU, Follow-up; GAF, Global Assessment of Functioning; GSD-SZ, Guided Self-Determination for Schizophrenia; IMR, Illness Management and Recovery; ITT, Intention-to-treat; MANSA, Manchester Short Assessment of Quality of Life; MHCS, Mental Health Confidence Scale; N/A, Not applicable; NR, Not reported; PANSS, Positive and Negative Syndrome Scale; PECC, Psychosis Evaluation Tool for Common Use by Caregivers; PSP, Personal and Social Performance Scale; QLS, Quality of Life Scale; QOLI, Quality of Life Inventory; QPR, The Questionnaire about the Process of Recovery; QPR-SF, The Questionnaire about the Process of Recovery – Short Form; RAS, Recovery Assessment Scale; RW, Recovery Workbook; SD, Standard deviation; SIAS, Social Interactions Anxiety Scale; TAU, Treatment as usual; W-QLI, Wisconsin Quality of Life Index; WHOQOL-BREF, World Health Organisation Quality of Life Instrument.

Discussion

This review examined the degree to which psychosocial interventions are effective in improving service user defined recovery and empowerment for people with psychosis. The review specified a priori that included studies would be limited to those that had assessed personal recovery using reliable and valid psychometric measures, developed in collaboration with service users. To our knowledge, this is the first review of its kind. A secondary aim was to evaluate the effectiveness of psychosocial interventions on other important outcomes that may be linked to personal recovery, including psychiatric symptoms, depression, anxiety, functioning and quality of life.

A systematic search of the literature identified a small number of RCTs (*n*=10) that had evaluated the effectiveness of psychosocial interventions on the personal recovery of service users, with limited evidence that psychosocial interventions improved personal recovery (*n*=3 studies) and empowerment (*n*=1 study) outcomes compared to routine care. When within-group pre-post effects were considered, large improvements in personal recovery were found following individual CT (*n*=2 studies), while small improvements were found for other recovery-focused psychosocial interventions (*n*=3 studies). The RW and the REFOCUS intervention led to very large and small improvements, respectively, in participants' perceptions of empowerment.

In relation to the secondary outcomes, significant group differences were found indicating that recovery-focused psychosocial interventions performed significantly better than control comparisons at improving psychiatric symptoms (*n*=4 studies), functioning (*n*=3 studies), and depression (*n*=1 study). When pre-post effects were

considered, there was evidence that psychosocial interventions were effective at improving psychiatric symptoms, depression, social anxiety, quality of life, and functioning. The most robust effects were found for psychiatric symptoms, where large improvements were found for group IMR (*n*=1 study), individual CT for psychosis (*n*=1 study), and individual EFC (*n*=1 study). This was followed by moderate to large improvements in depression and social anxiety for individual CT (*n*=2 studies). Finally, psychosocial interventions resulted in small to moderate improvement in functioning (*n*=2 studies) and small improvements in quality of life (*n*=5 studies).

Limitations of included studies

There were a number of limitations within the included studies that were likely to have introduced bias, thus findings should be interpreted with caution. Most studies did not find significant differences between groups on the primary outcome of personal recovery or several of the secondary outcomes. Small sample sizes within studies may have resulted in insufficient power to detect intervention effects, particularly if the effects were small. This was likely to be a more significant problem for studies where the drop-out rate was greater than 25%. Only a minority of studies published details regarding *a priori* statistical power calculations that anticipated drop-out. In addition, very few studies followed procedures to ensure fidelity to the intervention protocols, so it is possible that the implementation of the psychosocial interventions may have compromised their effectiveness.

It is also possible that where significant effects were reported, these may have been better ascribed to the common factors associated with taking part in a structured, therapeutic intervention rather than the unique psychosocial intervention per se. The

majority of included studies were vulnerable to this bias having evaluated their psychosocial interventions against routine care, and therefore the common therapeutic factors which may have benefitted the intervention groups were not controlled for in comparison groups. Indeed, there were no differences found between groups in the one study that did use an active control comparison group (Salyers et al., 2014).

Studies were unable to blind participants to treatment allocation making them vulnerable to performance bias, which also leads to overestimation of effect sizes (Higgins & Green, 2011). The risk of bias ratings showed a high number of unclear or high risk of bias ratings, suggesting that the overall study quality was fairly low. All studies used outpatient samples limiting the generalisability of findings to patients receiving acute care in inpatient environments. Generalisability was also compromised by high refusal rates for study participation, thus conclusions can only be drawn about individuals who engaged with the intervention. Finally, there was limited evidence available regarding longer-term effects of psychosocial interventions on outcomes, due to the lack of adequate follow-up.

Limitations of review

There were several limitations to the review itself. Only a small number of studies met inclusion criteria, and only two studies evaluated the same type of intervention, so meta-analysis was not performed. Only published studies were included which puts the review at risk of overestimating the effects of the interventions (Higgins & Green, 2011). Furthermore, results are based on data available in the published study reports, therefore missing data may have biased the review findings. Review inclusion criteria limited sampling to participants with diagnoses of schizophrenia, schizoaffective

disorder and other non-affective psychoses, limiting the generalisability of the findings beyond the study population and preventing a transdiagnostic approach (Barlow, Allen, & Choate, 2004). Finally, measurement of personal recovery may have introduced bias: only the QPR was designed specifically for a psychosis population, so it is possible that the RAS may lack sensitivity to detect changes in personal recovery in the study population. These issues highlight that more research is needed to examine if there are differences in recovery experiences across diagnostic categories.

Conclusions

This review highlights that research into personal recovery in psychosis remains at a preliminary stage. The findings from the review signal that current recovery-focused psychosocial interventions may have some benefit on improving the personal recovery outcomes of service users with psychosis. Interestingly, these interventions had more consistent effects on secondary outcomes related to recovery. In particular, there was support from both within-group effect sizes and significant group comparisons to suggest that recovery-focused interventions may be effective at improving psychiatric symptoms, functioning and depression. These findings have to be interpreted cautiously given the context of the risk of bias ratings which indicated that study quality was compromised by a high number of unclear or high risk of bias ratings.

Only a minority of studies found significant group differences on personal recovery. This raises the question of whether recovery-focused interventions are targeted towards personal recovery. Examination of within-group effect sizes suggested that at least half of the interventions influenced improvement in personal recovery, so it could simply be that treatment gains were as beneficial as those resulting from routine care. It is

notable that routine care, as described by study authors, often included access to other psychosocial interventions which may have also promoted personal recovery and confounded the results. Alternatively, it is possible that the personal recovery measures used in the studies, although expected to have high acceptability to service users, may be insufficient to detect changes in personal recovery. It has been noted that personal recovery is an idiosyncratic process (Leamy et al., 2011), presenting a measurement challenge. Another possibility is that psychosocial interventions did not have differential benefits over routine care because personal recovery is a dynamic process i.e. change occurs in different domains over a longer recovery journey. In this formulation, changes in psychiatric symptoms, depression, and functioning represent incremental steps, giving rise to later changes in recovery and empowerment. Thus short durations of study follow-up in the studies would not be sensitive to change. This is consistent with an emerging literature conceptualising recovery as a multi-stage journey (Leamy et al., 2011; Schrank & Slade, 2007).

Implications for research

Future research is warranted to establish what components of psychosocial interventions facilitate improvement at different points in the recovery journey. This "what works for whom" approach enables development of more targeted and personalised interventions varying according to service users' individual needs. Conceptualising recovery as a dynamic process suggests future studies would benefit from outcome measurement at more frequent time points and include longer periods of follow-up. A number of studies were excluded from the review because their outcome assessments did not include personal recovery measures developed in consultation with service users. The paucity of valid, reliable and acceptable measures of personal

recovery suggest more effort is required in establishing fit-for-purpose measures. Future studies should also incorporate larger sample sizes, active treatment control groups and measures to counter the effects of bias.

Implications for services

We will only truly know if recovery-oriented services are effective if they are evaluated in accordance with service user definitions of recovery. Going forward, personal recovery measures should be considered mandatory when evaluating interventions in research and clinical practice. If interventions can be shown to produce outcomes that are valuable to service users, then this is likely to enhance service user engagement (Neil et al., 2010), as well as contributing to the evidence base.

Declaration of interest
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Chapter 2: Empirical Journal Article

Self-stigma, decisional capacity and personal recovery in psychosis

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Objectives. To improve our understanding of the factors that promote personal recovery examining the relationships between self-stigma, symptomatic recovery, personal recovery and decisional capacity for treatment decisions in psychosis.

Design. A cross-sectional study was conducted to examine the relationships between study variables.

Methods. Twenty-four participants meeting criteria for schizophrenia, schizoaffective disorder or delusional disorder completed self-report measures of self-stigma, personal recovery and symptoms of emotional distress, as well as two semi-structured interviews assessing psychopathology and decisional capacity for treatment decisions. Correlational analyses were used to examine associations between the study variables. Linear regression analyses were conducted to examine the prediction of significant correlates on the understanding, appreciation and reasoning domains of decisional capacity.

Results. Self-stigma was positively associated with negative symptoms and emotional distress, whereas it was negatively associated with personal recovery and the reasoning domain of decisional capacity. Regression analysis indicated that excitement predicted appreciation of disorder and treatment.

Conclusions. The findings suggest that interventions aimed at promoting recovery from psychosis should target self-stigmatising beliefs and the role of emotion. The findings between excitement and reasoning may have implications for service engagement, although more research is needed to develop our understanding of the

psychological factors that are associated with decision-making, and new fit-for-purpose measures need to be developed.

Practitioner points

- Higher levels of self-stigma were significantly associated with poorer personal recovery, greater negative symptoms and increased emotional distress. Interventions that address self-stigmatising beliefs and the role of emotion are likely to promote recovery from psychosis.

- More research is needed to identify the psychological factors that are likely to influence treatment decision-making in people with psychosis.

Introduction

Recent policy developments initiated a drive to improve psychosocial care for individuals with mental health disorders. This shifts the focus from the dominant 'clinical recovery' service model, characterised by medicalised and paternalistic care, to a 'personal recovery' model that empowers service users. If this change is to be realised, mental health services will likely have to re-evaluate practices that disempower service users. For service users with diagnoses of psychosis, coercive practices regarding care and treatment are not uncommon (Kinderman, 2014). Reassigning power to service users in decisions about their care and treatment is consistent with modern conceptualisations of personal recovery. To date, there has been little psychological research regarding service users' decisional capacity for treatment decisions, yet we need to understand the psychological factors that may promote or impede decisional capacity if service providers are to support their service users' autonomy. Qualitative studies implicate self-stigma as having negative consequences for service users' involvement in treatment decisions. Given associations identified between self-stigma and markers of recovery from severe mental illness, self-stigma and personal recovery may influence decisional capacity for treatment decisions in psychosis. This has yet to be subjected to empirical investigation.

Personal recovery, evolved from the service user movement, advocates that service users with psychosis can progress towards living a meaningful life, even when psychiatric symptoms persist (Davidson, O'Connell, Tondora, Lawless, & Evans, 2005). Therefore, symptom reduction need not be the focus of recovery-oriented care. This challenges the traditional clinical recovery perspective which primarily seeks to achieve symptom remission whilst also resolving deficits in functioning

(Davidson et al., 2005). Service users agreed that management of symptoms is just one component contributing to a myriad of psychosocial factors considered essential for personal recovery (Law & Morrison, 2014). Empirical research supports a role for psychiatric symptoms in both clinical and personal recovery (Morrison et al., 2013), but symptom remission alone may not encapsulate recovery from psychosis. Indeed, personal recovery has been described as a journey with processes of developing awareness and acceptance of the mental health disorder, hope about the future, redefining the self, and becoming empowered as an active agent in one's life (Leamy, Bird, Le Boutillier, Williams, & Slade, 2011; Schrank & Slade, 2007).

Research suggests that endorsement of stigmatising beliefs about mental illness may act as a psychological barrier to personal recovery. Self-stigma denotes individuals' internalised negative beliefs, attitudes or expectations about their mental health disorder, based on public stereotypes of mental illness (Corrigan, Giffort, Rashid, Leary, & Okeke, 1999). Stereotypes include perceptions that people with psychosis are to be feared, considered unpredictable and worthy of ridicule (Pyle & Morrison, 2014). A survey of service users with diagnoses of psychosis across fourteen European countries found that 41.7% of respondents had internalised such stigmatised beliefs to a moderate or high degree (Brohan, Elgie, Sartorius, Thornicroft, & Group, 2010). Self-stigma has been conceptualised as involving three hierarchical concepts: awareness of negative stereotypes about mental health, agreement with them and application to the self (Corrigan, Larson, & Ruesch, 2009). It is thought that stereotypes are acquired through a process of social learning prior to the onset of mental health difficulties, and later become applied to the self when a mental health diagnosis is given (Link, Cullen, Struening, Shrout, & Dohrenwend, 1989). Research has shown that being labelled with a schizophrenia diagnosis is

linked to experiences of public stigma and self-stigma, and having the label may even compound the effects of the disorder (Imhoff, 2016; Link et al., 1989).

Cross-sectional research demonstrates that higher levels of self-stigma are linked to reductions in: hope (Lysaker, Roe, & Yanos, 2007); self-esteem (Corrigan, Watson, & Barr, 2006; Lysaker et al., 2007; Norman, Windell, Lynch, & Manchanda, 2011; Yanos, Roe, Markus, & Lysaker, 2015); meaning in life (Hasson-Ohayon et al., 2014; Or et al., 2013); self-efficacy (Corrigan et al., 2006; Vauth, Kleim, Wirtz, & Corrigan, 2007); empowerment (Vauth et al., 2007); personal autonomy (Munoz, Sanz, Perez-Santos, & de los Angeles Quiroga, 2011); quality of life (Park, Bennett, Couture, & Blanchard, 2013); psychosocial treatment adherence (Tsang, Fung, & Chung, 2010); activity levels (Moriarty, Jolley, Callanan, & Garety, 2012); and social functioning (Munoz et al., 2011). A systematic review found moderate to large effect sizes for the associations of self-stigma with many of these psychosocial variables (Livingston & Boyd, 2010). Furthermore, there is evidence that service users who perceive discrimination by others have greater reliance on avoidant coping strategies, such as secrecy and withdrawal (Kleim et al., 2008). This finding is consistent with qualitative research which found that service users may be inclined to avoid disclosing their disorder because of fears of negative evaluation and rejection from others (Pyle & Morrison, 2014). Therefore, self-stigma is associated with factors that are potentially inconsistent with aspects of personal recovery. Interestingly, a recent randomised controlled trial demonstrated that cognitive therapy adapted to reappraise self-stigmatising beliefs about psychosis significantly improved personal recovery outcomes (Morrison et al., 2016).

Thus, self-stigma may have a negative impact on personal recovery from severe mental illness, an association that may be specific to recovery from psychosis - as

defined and measured by service users. However, associations between self-stigma and clinical recovery may be less clear (Park et al., 2013). Systematic review evidence shows that higher levels of self-stigma were significantly associated with increased symptom severity in 50 studies examining the relationships between these variables (Livingston & Boyd, 2010). Notably, the majority of studies included in the review did not find significant associations between self-stigma and indices of clinical recovery such as number of hospitalisations or functioning (Livingston & Boyd, 2010). In terms of symptomatology, self-stigma has been positively associated with positive symptoms, general psychopathology and depression (Cavelti, Kvrgic, Beck, Rüsch, & Vauth, 2012; Corrigan et al., 2006; Lysaker et al., 2007; Park et al., 2013). While Lysaker et al. (2007) found that increased self-stigma was also related to greater negative symptoms, other studies report the absence of a relationship between self-stigma and negative symptoms (Park et al., 2013).

The personal recovery literature highlights that, for individuals experiencing mental health difficulties, taking ownership of their lives and making their own decisions about care and treatment are significant processes in the recovery journey (Leamy et al., 2011; Schrank & Slade, 2007). However, in the current landscape, engagement in treatment decisions for service users with diagnoses of psychosis centres on issues of 'capacity' and 'consent'; concepts defined within a legal context. In Scotland, a person will have 'incapacity' if judged as being incapable of acting on, making, understanding, communicating or retaining the memory of decisions in order to give or refuse their consent (Scottish Executive, 2000). A high rate of incapacity in people admitted to mental health inpatient units, particularly those with a schizophrenia diagnosis (Owen et al., 2008), presents a challenge to service user participation in treatment decisions.

Research into developing a broader understanding of the factors that may facilitate or impede decisional capacity is at a preliminary stage. Incapacity for treatment decisions has predominantly been associated with clinical variables such as a diagnosis of psychosis, disorder severity, delusional experiences, psychopathology, impaired cognitive abilities, poor insight, involuntary admissions to psychiatric care and treatment refusal (Okai et al., 2007; Owen et al., 2009). Owen et al. (2009) found that greater psychopathological symptoms were significantly associated with reduced decisional capacity for treatment decisions with a large effect size (hedges *g*=1.07). A systematic review by Okai et al. (2007) indicated that a small number of studies found positive associations between depression and increased decisional capacity. There is, however, little known about the potential influence of psychological variables, including self-stigma, on decisional capacity. Consistent with the legal definition, tools developed to assess capacity for treatment decisions emphasise understanding and reasoning skills (Mental Welfare Commission for Scotland, 2010). The most researched and well-known is the MacArthur Competence Assessment Tool for Treatment (MacCAT-T) (Grisso & Applebaum, 1998). Its focus on assessment of cognitive abilities may compromise its utility in detecting psychological influences on treatment decision-making, however it is currently recommended as the gold standard in decisional capacity research.

It has been highlighted that many people with severe mental health difficulties perceive treatment interventions as coercive, whereby they may not fully understand the intervention or believe it will benefit them (Corrigan, 2002). Moreover, perceived coercion is often associated with service users not 'complying' with their treatment (Corrigan, 2002). Cognitive models suggest that service users with diagnoses of psychosis may be less likely to agree they have a need for treatment if doing so

activates self-stigmatising beliefs (Morrison, 2001). This reluctance, in turn, may lead to concerns being raised about their ability to make informed decisions about their care (Shek, Lyons, & Taylor, 2010), increasing the likelihood of coercive treatment and potentially compromising the recovery process. Indeed, qualitative interviews about experiences of treatment decision-making identified that self-stigma made it difficult for service users with diagnoses of psychosis to engage in the decision-making process, forcing them to assume a passive role in care planning (Dunion, & McArthur, 2012; Stovell, Wearden, Morrison, & Hutton, 2016).

Despite these challenges, legislation exists to protect service users' rights to autonomy entitling them to appropriate support to enhance their involvement in treatment decisions. Guidelines have been published recommending 'supported decision-making' - also referred to as 'shared decision-making' - a collaborative approach to care and treatment that places significance on service users' rights, preferences and values (Mental Welfare Commission for Scotland, 2016). Perhaps synonymous with the progression from clinical to personal recovery, this approach marks a departure from the traditional model of paternalistic healthcare in which treatment decisions were based on what healthcare professionals considered to be best for the 'patient'. Encouragingly, meta-analytic evidence indicates that supported decision-making can improve outcomes related to empowerment (Stovell, Morrison, Panayiotou, & Hutton, 2016), and thus the approach may fit well with the conceptualisation of personal recovery. However, a greater understanding of the factors contributing to effective supported decision-making is needed (Scottish Public Services Ombudsman, 2017). The potential links between subjective appraisals of psychosis (i.e. self-stigma) and judgements of decisional capacity have yet to be examined. If they exist, then developing effective strategies to reduce self-

stigma may have benefits in relation to improving and supporting both decisional capacity and personal recovery.

In summary, the existing literature links psychiatric symptoms to personal recovery, self-stigma and decisional capacity. A growing evidence base indicates that self-stigma may have a negative impact on a number of psychosocial outcomes linked to recovery, and a recent RCT signals that overcoming stigmatising beliefs and being empowered in one's own treatment journey leads to recovery outcomes that are meaningful to service users (i.e. personal recovery). However, self-stigma and personal recovery have not been investigated in terms of their relationship to decisional capacity for treatment. Thus far, decisional capacity research has focused on clinical correlates with little known about the psychological variables that that may affect a person's capacity to be involved in treatment decisions. Qualitative data suggests that self-stigma may play a significant role in treatment decision-making, but this relationship has not been examined in quantitative research. The present study aims to address this by examining the relationships between self-stigma, personal recovery, psychiatric symptoms and decisional capacity for treatment. The following research questions were asked:

1) Is self-stigma significantly associated with symptomatic and personal recovery?

2) Is self-stigma significantly associated with decisional capacity for treatment decisions?

3) Do self-stigma, personal recovery and psychiatric symptoms predict decisional capacity?

Method

Ethical approval was granted by South East Scotland Research Ethics Committee (Appendix 6).

Participants

Participants were recruited from community mental health teams and in-patient settings across East and South East Scotland, and a voluntary service in South East Scotland. Eligible participants were aged 18-65 years and met International Classification of Diseases – tenth revision (ICD-10) (World Health Organisation, 1992) criteria for schizophrenia, schizoaffective disorder or delusional disorder. Participants also had sufficient proficiency in the English language to allow them to complete the study measures, and were able to give informed consent to participate in research. Participants were excluded if they had organic impairment, a primary diagnosis of substance-induced psychosis, a learning disability or autism spectrum disorder, or a current acute relapse of psychotic symptoms.

There was a 12 month window of recruitment into the study over the period August 2015 to August 2016. The early phase of recruitment took place in the health board in which the researcher was based as a Trainee Clinical Psychologist. This covered a large rural area in South East Scotland with a low population density, in which participants received care from generic community mental health teams, or those with greater chronicity from a psychiatric rehabilitation service offering inpatient and outpatient services. Participation in the study involved completion of two interview protocols and three standardised questionnaires for which there was no payment or incentives offered. These factors presented a challenge to recruiting from a clinical population with an already known limited uptake for participation in research. More than half of the study participants (*n*=15) were recruited from the original recruitment

site. However, on approaching the mid-point of the planned recruitment period, it became apparent that the rate of recruitment was unlikely to achieve the sample size required to ensure adequate power. Subsequently, ethical approval was sought and granted for recruitment to be extended into two semi-rural health boards in East Scotland. One health board yielded only one further participant due to possible saturation of participants with a high volume of research being carried out with the target population. Efforts were therefore focused in the final three months of the recruitment period on recruiting from a third health board from which a further nine participants completed study measures. Recruitment seemed to be facilitated by referrals being made by clinical psychologists working within a specialist psychosis service in which no other research (known to the researcher) was ongoing at the time of recruitment. Challenges were encountered across all three recruitment sites with the study measures taking longer to complete than anticipated, which meant that the majority of participants were seen on more than one occasion to complete the consent form and study measures. However, this did not lead to attrition which suggests that the study was acceptable to participants, and highlighted their personal commitment to taking part in this research.

Measures

Internalised Stigma of Mental Illness Inventory (ISMI) (Ritsher, Otilingham, & Grajales, 2003) (Appendix 11)

The ISMI is a 29-item self-report measure that assesses experience of self-stigma across five subscales: alienation, stereotype endorsement, discrimination experiences, social withdrawal and stigma resistance. Each item is rated for agreement on a 4-point Likert scale ranging from 1=strongly disagree to 4=strongly agree. Total scores or individual scores across each of the subscales can be evaluated. Higher scores indicate increased levels of self-stigma. The ISMI has

been reported to have excellent internal consistency (α = .90) and test-retest reliability (α = .92) (Brohan et al., 2010). In the present study, a high degree of internal consistency (Cronbach's α = .81) was found across the items making up the ISMI total score.

Recovery Assessment Scale (RAS) (Giffort, Schmook, Woody, Vollendorf, & Gervain, 1995) (Appendix 12)

The RAS is a 41-item self-report measure that assesses service users' perceptions of personal recovery across five subscales: personal confidence and hope; willingness to ask for help; goal and success orientation; reliance on others and no domination by symptoms. Each item is rated for agreement on a 5-point Likert scale ranging from 1=strongly disagree to 5=strongly agree. The RAS has been found to have good concurrent validity, internal consistency (α = .93) and test-retest reliability (r = .88) over a period of fourteen days (Corrigan et al., 1999). In the present study, the internal consistency was good (α = .83).

MacArthur Competence Assessment Tool for Treatment (MacCAT-T) (Grisso, Appelbaum, Mulvey, & Fletcher, 1995) (Appendix 13)

The MacCAT-T is a semi-structured interview that offers a standardised method of assessing an individual's competence to make treatment decisions. The interview comprises information being disclosed to participants about their disorder, the recommended treatment, its benefits and risks, and an alternative treatment. For the purposes of measuring decisional capacity in the current study, participants were given information about a hypothetical research treatment and an alternative, and were asked to apply this information to their own situation in order to make a decision about which treatment they would choose. Participants were asked a number of questions about their decision-making process so that ratings could be

made across four capacities that have been related to decisional capacity: understanding disorder and treatment information, appreciation of disorder and treatment, reasoning and weighing up consequences, and expressing a choice. The administration and scoring was carried out by the main author in accordance with the MacCAT-T manual (Grisso & Appelbaum, 1998). The MacCAT-T authors recommend against calculation of a total score, but ratings can be given on each of the four domains as follows: Understanding (0-6); Appreciation (0-4); Reasoning (0-8); and Expressing a choice (0-2). Higher scores on the MacCAT-T indicate better capacity to make treatment decisions. The MacCAT-T was selected for use in the present study because it is recommended as the best (given that it assesses all four abilities related to decision-making) and most researched tool for assessing decision-making capacity for treatment decisions (Dunn *et al.*, 2006). High inter-rater reliabilities have been reported for each of the subscales in the assessment tool (0.99 for understanding, 0.87 for appreciation, 0.91 for reasoning, and 0.97 for expressing a choice). It has also been shown to be a valid and clinically feasible measure (Grisso et al*.,* 1997).

Positive and Negative Syndrome Scale (PANSS) (Kay, Flszbein, & Opfer, 1987)

The PANSS was used to establish the level of psychopathology in the sample. This is a semi-structured interview consisting of 30 items to assess participants' severity of symptoms over the preceding seven days. Severity of symptoms are rated by the interviewer on a seven-point Likert scale (1 = absent to 7 = extreme), with higher scores indicating greater severity in psychopathology. In the current study, the PANSS was analysed according to the five factor structure validated by van der Gaag et al. (2006) which comprises positive symptoms, negative symptoms,

cognitive symptoms, excitement and emotional distress. The internal consistency in the present study was excellent (α = .91).

Depression Anxiety Stress Scales – 21 item version (DASS-21) (Lovibond & Lovibond, 1995) (Appendix 14)

The DASS-21 is a self-report measure of severity of symptoms of depression, anxiety and stress over the seven preceding days. It has been reported to have high internal consistency, ranging from 0.87 to 0.94 in a clinical population (Antony, Bieling, Cox, Enns, & Swinson, 1998). The full 42-item instrument on which it was based was reported to have internal consistency in a non-clinical population ranging from α = .81 to .91 (Lovibond & Lovibond, 1995). In the present study, the internal consistency was α = .92.

Procedure

Participants contacted the researcher directly in response to a study poster (Appendix 7), or were referred by a member of their care team. Self-referring participants gave verbal consent for the researcher to confirm their suitability for inclusion in the study with a member of their care team. Potential participants approached by a member of their care team were offered information about the study and given an information leaflet (Appendix 8). Those who gave verbal consent for the researcher to contact them were given a minimum of 24 hours to consider the information before the researcher called them by telephone to discuss the study and answer any questions. Those expressing an interest to take part in the study met with the researcher at a clinic location or at home. The study measures were commenced once written informed consent was obtained (Appendix 9). Participants had the option to have the measures carried out over more than one occasion.

Statistical power

An a priori calculation using G*Power3.1 indicated that a sample of 36 participants would be required to detect a large effect ($f^2 = 0.35$) in a linear regression analysis of three predictor variables (ISMI, PANSS and DASS-21) on decisional capacity (MacCAT-T), with a power level of 0.8 and alpha level of 0.05.

Statistical analyses

Data was analysed using SPSS 21 for Windows. Kolmogorov-Smirnov tests were performed to establish if data were normally distributed. MacCAT-T domains of appreciation and expressing a choice violated the assumption of normality, thus were analysed using nonparametric statistical tests. All other study variables were normally distributed and were analysed using parametric tests. The relationships between continuously distributed study variables were examined using correlational analyses; and the effect of gender on study variables was examined using independent samples t-tests. Due to the small sample size, bootstrapped correlational analyses were also conducted. Where significant correlations between variables were found, linear multiple regression was performed to examine prediction of decisional capacity. Regression analyses were conducted using the enter method.

Results

Sample characteristics and descriptive statistics

The process of recruitment is displayed in Figure 1. A total of twenty four participants were recruited from two NHS health boards (one rural and one semi-rural). Fourteen males (58.3%) and ten females (41.7%) completed study measures. The mean age of the sample was 43.21 years (SD 10.77; range 26-63). The primary psychiatric diagnoses of participants were schizophrenia (*n*=19) and schizoaffective disorder (*n*=5). The mean duration of illness was 15.83 years (SD 9.94; range 1-35). Demographic characteristics of the sample are displayed in Table 1. Scores on the ISMI, RAS, DASS-21 and all five PANSS subscales were normally distributed, whereas scores on the MacCAT-T appreciation and expressing a choice domains were not. Table 2 reports descriptive statistics for all measures. The mean total ISMI score in our sample (mean 2.35, SD 0.44) was similar to that found in an American sample of 100 mental health service users with a diagnoses of 'serious mental illness' (mean 2.3, SD 0.4) (Drapalski et al., 2013). ISMI scores greater than 2.5 have been defined as moderate to severe self-stigma, while scores in the range of 2.0 – 2.5 have been defined as mild self-stigma (Ritsher & Phelan, 2004), indicating that our sample fell within the mild self-stigma range. The mean total DASS-21 score was 53.67 (SD 29.16), which compares to 18.38 (SD 18.82) obtained from a sample of 1771 members of the general adult UK population (Crawford & Henry, 2003). The mean total understanding score in our sample was 5.06 (SD 0.45) which indicated better understanding ability than a sample of 40 inpatients with diagnoses of schizophrenia or schizoaffective disorder (mean 4.33, SD 1.35), but reduced understanding ability compared to a community sample of 40 people without mental health diagnoses (mean 5.60, SD 0.66) (Grisso & Appelbaum, 1998). The mean total reasoning score in our sample was 5.42 (SD 1.41), which indicated better reasoning ability than the inpatient sample (mean 5.20,

SD 2.42) but reduced reasoning ability compared to the healthy community sample (mean 6.15, SD 1.69) (Grisso & Appelbaum, 1998). Mean scores for the PANSS indicated that levels of psychopathology were low to moderate in the sample. Male participants had significantly higher scores than females on the excitement subscale of the PANSS (t=2.40, p=.025). There were no significant gender differences on any other study variables. Participants' age was also not associated with any study variables.

Figure 1. Study flow diagram

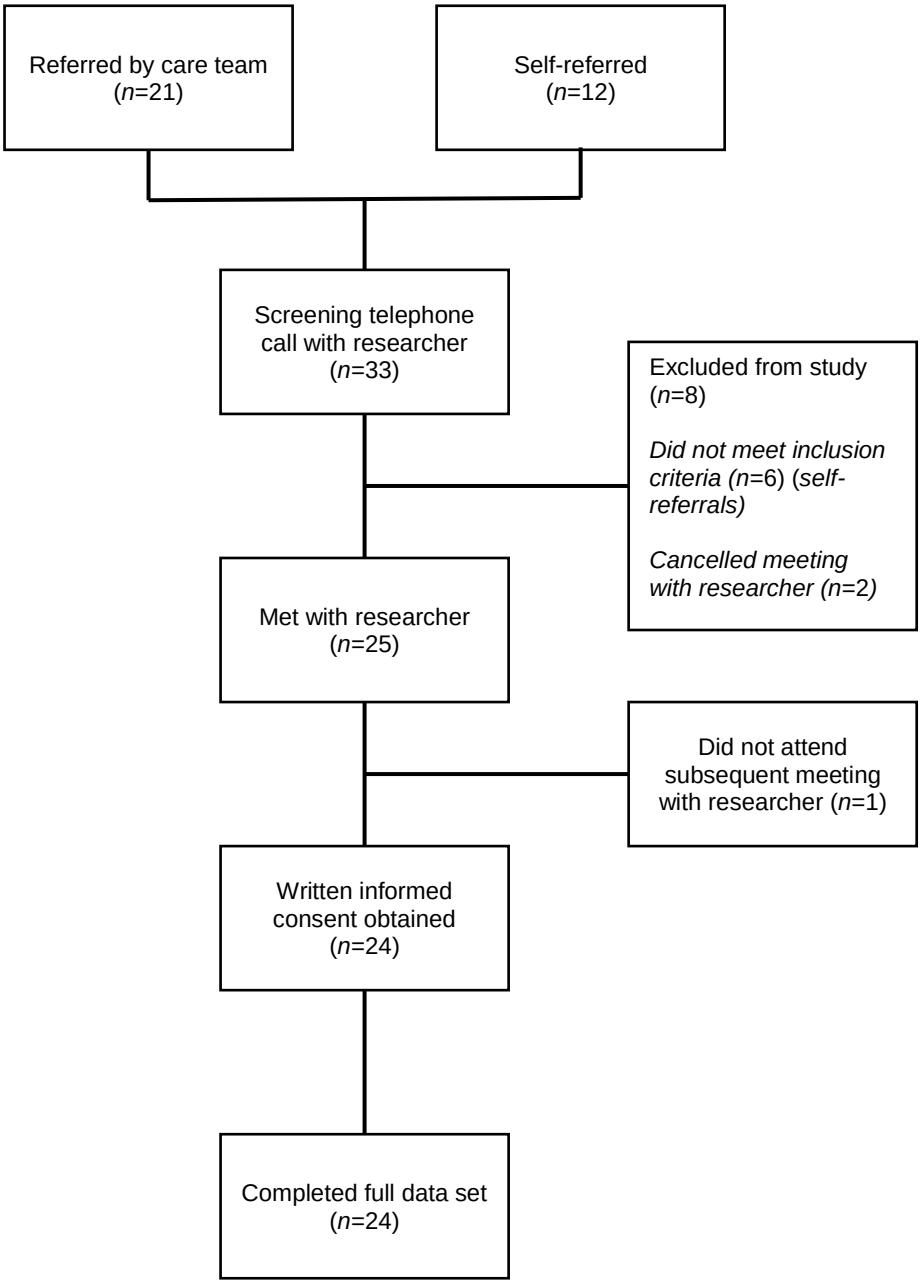

Table 1. Participant characteristics (*n*=24)

Variable	Frequency	
	n	%
Gender		
Male	14	58.3
Female	10	41.7
Ethnicity		
White British	23	95.8
White other	1	4.2
Relationship status		
Single	16	66.7
Married	2	8.3
In a relationship	2	8.3
Divorced	4	16.7
Employment status		
Employed	2	8.3
Unemployed	11	45.8
Student	3	12.5
Retired	5	20.8
Unable to work	3	12.5
Primary psychiatric diagnosis		
Schizophrenia	19	79.2
Schizoaffective disorder	5	20.8
Medication status		
Taking antipsychotic medication	24	100
Not taking antipsychotic medication	0	0

Table 2. Scores on study measures (n=24)

Variable	Range	Mean (SD)
ISMI		
Total item score	1.41 - 3.00	2.35 (0.44)
Total item score without stigma resistance	1.38 - 3.29	2.44 (0.50)
Alienation	1.00 - 3.50	2.57 (0.71)
Stereotype endorsement	1.14 - 2.57	1.95 (0.42)
Discrimination experiences	1.20 - 3.60	2.69 (0.56)
Social withdrawal	1.17 - 4.00	2.68 (0.72)
Stigma resistance	1.00 - 2.80	1.94 (0.41)
RAS		
Total score	125 - 182	152.46 (14.59)
Personal confidence and hope	21 - 39	30.83 (4.92)
Willingness to ask for help	3 - 15	11.83 (3.27)
Goal and success orientation	13 - 23	19.04 (2.42)
Willingness to rely on others	12 - 20	16.33 (2.12)
No domination by symptoms	4 - 15	9.38 (2.79)
DASS-21		
Total	4 - 106	53.67 (29.16)
Depression	0 - 40	19.08 (13.41)
Anxiety	2 - 36	15.08 (10.28)
Stress	0 - 38	19.50 (10.01)
MacCAT-T		
Understanding	3.95 - 6.00	5.06 (0.45)
Reasoning	2.00 - 8.00	5.42 (1.41)
PANSS		
Total	45 - 107	65.25 (18.18)
Positive symptoms	10 - 28	16.54 (5.85)
Negative symptoms	7 - 28	14.00 (4.99)
Cognitive symptoms	9 - 34	16.54 (6.95)
Excitement	4 - 12	6.21 (2.43)
Emotional distress	7 - 17	11.96 (2.87)

Note: DASS-21, Depression, Anxiety, Stress Scales – 21 item version; ISMI; Internalised Stigma of Mental Illness Inventory; MacCAT-T, MacArthur Competence Assessment Tool for Treatment; PANSS, Positive and Negative Syndrome Scale; RAS, Recovery Assessment Scale; SD, Standard Deviation.

Correlational analyses

Correlations between study variables are reported in Table 3. Bootstrapped analyses are reported in Appendix 15. A large and significant correlation was found for perceptions of self-stigma and ratings of personal recovery, with higher levels of self-stigma associated with reduced recovery (r = -0.533, p = 0.007; Bootstrapped 95% CI = -0.755 to -0.252). Higher levels of self-stigma were also significantly associated with reduced reasoning ability on the MacCAT-T (r = -0.441, p = 0.031; Bootstrapped 95% CI = -0.704 to -0.082), greater negative symptoms (r = 0.501, p = 0.013; Bootstrapped 95% CI = 0.218 to 0.740), and increased emotional distress as measured by the PANSS (r = 0.700, p < .001; Bootstrapped 95% CI = 0.470 to 0.851) and the DASS-21 (r = 0.601, p = 0.002; Bootstrapped 95% CI = 0.312 to 0.791). These associations remained significant when stigma resistance items were omitted from the self-stigma variable.

MacCAT-T understanding was significantly correlated with cognitive symptoms (r = -0.435, p = 0.033; Bootstrapped 95% CI = -0.728 to 0.062) and excitement (r = -0.573, p = 0.003; Bootstrapped 95% CI = -0.859 to -0.042). MacCAT-T appreciation was significantly associated with positive symptoms (ρ = -0.494, p = 0.014; Bootstrapped 95% CI = -0.738 to -0.065), cognitive symptoms (ρ = -0.463, p = 0.023; Bootstrapped 95% CI = -0.728 to -0.090), reasoning (ρ = 0.435, p = 0.034; Bootstrapped 95% CI = 0.019 to 0.724) and expressing a choice (ρ = 0.411, p = 0.046; Bootstrapped 95% CI = -0.154 to 0.808). Participants were more likely to show appreciation of their disorder and treatment when they had fewer positive and cognitive symptoms, while greater appreciation of the disorder and treatment was linked to better abilities in reasoning and expressing a choice.

Unexpectedly, personal recovery was not significantly correlated with any other study variable other than self-stigma. Given the size of the correlation between self-stigma and recovery, partial correlations were conducted to determine if the relationships between self-stigma and emotional distress (DASS-21 and PANSS), reasoning and negative symptoms remained statistically significant after controlling for personal recovery. Results indicated that, when personal recovery was controlled for, the significant association between self-stigma and reasoning ability was lost (r = -0.398, p = 0.060) (Table 4). In contrast, there was no significant weakening of the associations of self-stigma with emotional distress on the DASS-21 (r = 0.511, p = 0.013) or PANSS (r = 0.630, p = 0.001) when personal recovery was entered as a control variable, whereas the association between self-stigma and negative symptoms became marginally significant (r = 0.411, p = 0.052). These findings suggest that the relationship between self-stigma and reasoning ability is accounted for by a person's level of recovery, whereas emotional distress makes a unique contribution to the variance in self-stigma over and above the contribution of recovery. There was a marginally significant trend in the data indicating that negative symptoms may also uniquely contribute to self-stigma independently of its effect on recovery.

Table 3. Correlation matrix for all variables included in the analysis

	ISMI	ISMI - SR	RAS	DASS	MacCAT understand	MacCAT apprec.	MacCAT reason	MacCAT choice	PANSS positive	PANSS negative	PANSS cognitive	PANSS excitement	PANSS emotion
ISMI	-												
ISMI – SR	0.989**	-											
RAS	-0.533**	-0.506*	-										
DASS	0.601**	0.608**	-0.376	-									
MacCAT understand	-0.147	-0.173	-0.040	-0.216	-								
MacCAT appreciation	-0.141	-0.175	-0.097	-0.372	0.281	-							
MacCAT reasoning	-0.441*	-0.405*	0.210	-0.248	0.350	0.435*	-						
MacCAT choice	-0.131	-0.127	-0.138	-0.200	-0.123	0.411*	0.322	-					
PANSS positive	0.299	0.322	-0.248	0.710**	-0.360	-0.494*	-0.160	-0.216	-				
PANSS negative	0.501*	0.502*	-0.323	0.634**	0.031	-0.080	-0.259	-0.167	0.462*	-			
PANSS cognitive	0.251	0.251	-0.189	0.679**	-0.435*	-0.463*	-0.330	-0.284	0.825**	0.473*	-		
PANSS excitement	-0.028	0.001	-0.033	0.092	-0.573**	-0.111	-0.343	-0.116	0.435*	-0.054	0.479*	-	
PANSS emotion	0.700**	0.669**	-0.396	0.641**	-0.125	-0.167	-0.264	0.086	0.517**	0.584**	0.514*	0.26	-

Note: DASS, Depression, Anxiety, Stress Scales 21-item version total scores; ISMI, Internalised Stigma for Mental Illness Inventory total mean item scores; ISMI – SR, ISMI total mean item scores minus stigma resistance items; RAS, Recovery Assessment Scale total scores; MacCAT understand, MacArthur Competence Assessment Tool for Treatment understanding domain scores; MacCAT apprec., MacArthur Competence Assessment Tool for Treatment appreciation domain scores; MacCAT reason, MacArthur Competence Assessment Tool for Treatment reasoning domain scores; MacCAT choice, MacArthur Competence Assessment Tool for Treatment expressing a choice domain scores; PANSS positive, Positive and Negative Syndrome Scale positive symptoms subscale scores; PANSS negative, Positive and Negative Syndrome Scale negative symptoms subscale scores; PANSS cognitive, Positive and Negative Syndrome Scale cognitive symptoms subscale scores; PANSS excitement, Positive and Negative Syndrome Scale excitement subscale scores; PANSS emotion, Positive and Negative Syndrome Scale emotional distress subscale scores *Correlation is significant at the 0.05 level. **Correlation is significant at the 0.01 level.

Table 4. Results of partial correlation controlling for personal recovery total scores

	ISMI	ISMI-SR	DASS	MacCAT reasoning	PANSS negative	PANSS emotion
ISMI	-	0.986**	0.511**	-0.398	0.411*	0.630**
ISMI – SR		-	0.522**	-0.354	0.414	0.591**
DASS			-	-0.186	0.585**	0.578**
MacCAT reasoning				-	-0.207	-0.202
PANSS negative					-	0.525**
PANSS emotion						-

Note: DASS, Depression, Anxiety, Stress Scales 21-item version total scores; ISMI, Internalised Stigma for Mental Illness Inventory total mean item scores; ISMI – SR, ISMI total mean item scores minus stigma resistance items; MacCAT reasoning, MacArthur Competence Assessment Tool for Treatment reasoning domain scores; PANSS negative, Positive and Negative Syndrome Scale negative symptoms subscale scores; PANSS emotion, Positive and Negative Syndrome Scale emotional distress subscale scores.
*Correlation is significant at the 0.05 level. **Correlation is significant at the 0.01 level.

Regression analyses

Based on the results of the correlational analyses, three linear regression analyses were conducted. Age and gender were entered as predictors in the first blocks, and the significant correlates of each of the dependent variables understanding, appreciation and reasoning were entered in the second blocks (Table 5). A post-hoc calculation of statistical power was conducted based on the equation set out by Green (1991): $N \geq (8/f^2) + (m-1)$, where $f^2 = 0.02$, 0.15, and 0.35 for small, medium and large effects, and m represents the number of predictor variables. This indicated that a sample size of 26 participants provided sufficient power to detect large effects in the MacCAT-T understanding, appreciation and reasoning regression analyses with 4 predictor variables. Inspection of the respective regression plots, tolerance and VIF statistics indicated that assumptions of normality, linearity and homoscedasticity were met (Appendix 16). Tolerance

statistics were >0.2 satisfying the recommendations of Menard (1995), and were well above the 0.10 recommended by Tabachnick and Fidell (2013). As displayed in Table 5, linear regression analysis showed that excitement made a significant contribution to the prediction of the understanding domain of decisional capacity (β = -0.663, p = 0.023). In contrast, age, gender and cognitive symptoms did not make a significant contribution to the model. Thus, increasing severity of excitement symptoms had a negative impact on participants' understanding of their disorder and treatment information. No significant predictors emerged for the appreciation domain of decisional capacity. There was a marginally significant finding suggesting a signal for self-stigma making a unique contribution to the prediction of the reasoning domain of decisional capacity (β = -0.482, p = 0.076). There was no indication that age, gender or personal recovery uniquely contributed to the prediction of reasoning.

Table 5. Regression analyses for decisional capacity domains by predictors

MacCAT-T domain	Adjusted R^2	Predictor	β	*P*
Understanding	0.313	Constant		.000
		Age	0.043	0.847
		Gender	-0.326	0.186
		PANSS cognitive symptoms	-0.129	0.549
		PANSS excitement	-0.663	0.023
Appreciation	0.240	Constant		.000
		Age	0.102	0.621
		Gender	-0.057	0.779
		PANSS cognitive symptoms	-0.269	0.438
		PANSS positive symptoms	-0.319	0.361
Reasoning	0.030	Constant		.066
		Age	0.043	0.849
		Gender	0.026	0.908
		Self-stigma (Total ISMI)	-0.482	0.076
		Personal recovery (Total RAS)	-0.049	0.848

Note: ISMI, Internalised Stigma of Mental Illness Inventory; PANSS, Positive and Negative Syndrome Scale; RAS, Recovery Assessment Scale.

Discussion

The current study set out to improve our understanding of the psychological factors that may influence decisional capacity and recovery in service users with diagnoses of psychosis, focusing on a definition of recovery acceptable to service users. Firstly, we examined if self-stigma was associated with both personal recovery and symptomatic recovery in our sample, given that previous authors have highlighted mixed findings in the empirical literature regarding the latter (Park et al., 2013). Secondly, we extended the scope of the current literature, by investigating if a relationship existed between service users' endorsement of self-stigmatising beliefs and their capacity to make decisions about their mental health treatment. Finally, we explored if self-stigma, personal recovery and psychiatric symptoms could predict service users' decisional capacity for treatment decisions. This is pertinent, given the emphasis on the role of empowerment in modern conceptualisations of recovery, and findings from qualitative research suggesting that self-stigma may impede service users' involvement in treatment decisions (Stovell et al., 2016).

Consistent with previous research (Munoz et al., 2011), the current study found a strong, negative association between self-stigma and personal recovery. This highlights that personal and social meanings attached to having a diagnosis of psychosis by service users informs their personal adaptation to the disorder. Evidence is emerging that the effects of self-stigma on personal recovery may be mediated by feelings of hopelessness, shame, and reduced self-esteem (Vass et al., 2015; Wood, Byrne, Burke, Enache, & Morrison, 2017). Given this, it was surprising that we did not find significant correlations between personal recovery and measures of emotional distress, however this may be a nuance of our sample.

While there was no association with positive symptoms, increased self-stigma was significantly associated with greater negative symptoms and emotional distress. This is consistent with other studies that have reported significant associations between self-stigma and depressed mood (e.g. Ritsher & Phelan, 2004). Furthermore, the finding that self-stigma was linked to emotional distress but not positive symptoms seems to be synchronous with studies reporting that post-psychotic depression (PDD) often follows individuals' recovery from positive symptoms, with 50% experiencing PDD following the first episode of psychosis (Birchwood, Iqbal, Chadwick, & Trower, 2000). Relevant to our own findings regarding self-stigma, Iqbal, Birchwood, Chadwick, & Trower (2000) found that it was the presence of negative appraisals about psychosis, involving loss of social status, a sense of entrapment and feelings of shame, that predicted who developed PDD. Similarly, appraising psychosis as uncontrollable and entrapping was associated with social anxiety experienced after the first psychotic episode (Birchwood et al., 2006). Given that these effects have been observed following the first psychotic episode and soon after diagnosis, it suggests that the endorsement of self-stigma may form part of a psychological reaction to the diagnosis itself, leading to a pathway of emotional distress (Birchwood, 2003; Birchwood et al, 2000; Upthegrove, Marwaha, & Birchwood, 2016). Indeed, receipt of a diagnostic label has been identified as a catalyst for self-stigma, whereby negative stereotypes about mental illness, acquired through earlier social learning, become applied to the self (Corrigan, 2007; Link et al., 1989). It has been argued that application of the diagnostic label promotes a sense of difference, alienation from those who do not have the label, and a loss of social status, while also giving rise to discriminatory experiences by others including rejection and exclusion (Link & Phelan, 2001).

Thus, receiving a clinical diagnosis seems to provide the context for the activation of self-stigma (Wood, Byrne, & Morrison, 2017). The diagnosis itself can be a source of interpersonal threat with service users fearing rejection or devaluation if it becomes known to others (Birchwood et al., 2006). As a result, service users may employ maladaptive coping strategies to 'protect' themselves from the stigmatising label (Link et al., 1989) which may have serious implications for service engagement and recovery. It has been argued that service users with severe mental illness may stay away from services or delay help-seeking in order to avoid a stigmatising diagnosis (Corrigan, 2004; Corrigan, 2007). Indeed, a recent systematic review found that self-stigma was negatively associated with help-seeking, and was a barrier to service users accessing appropriate care (Clement et al., 2015). Non-disclosure of disorder, concealment, denial, and social withdrawal were found to be strategies used by service users at risk of or experiencing first-episode psychosis to avoid negative societal reactions about their disorder (Gronholm, Thornicroft, Laurens, & Evans-Lacko, 2017). Empirical research suggests that having limited awareness of the presence of schizophrenia may be adaptive in the context of self-stigma: Lysaker at al. (2007) found that, for those with schizophrenia spectrum disorders who hold self-stigmatising beliefs about mental illness, reduced insight into the disorder was associated with greater hope about the future and improved self-esteem, while better insight seemed to have deleterious effects on hope and self-esteem. Interestingly, both the high and low insight groups had significantly fewer social relationships than a third group who had high insight but did not endorse self-stigmatising beliefs about mental illness. Thus, reduced insight may serve to protect self-esteem and hope, but as a safety strategy it is counterproductive for social functioning.

Contrary to study hypotheses, self-stigma was negatively associated with only the reasoning domain of decisional capacity, but not understanding, appreciation or expressing a choice in treatment. The only other significant correlates of decisional capacity were psychiatric symptoms: understanding was negatively associated with cognitive symptoms and excitement, while appreciation was negatively associated with positive symptoms and cognitive symptoms. In the regression analyses, the only significant model that emerged was for PANSS excitement as a predictor of understanding. The excitement factor comprised items including poor impulse control, hostility and uncooperativeness. Therefore, those items may be proxies for engagement with treatment, with lower scores on these items implying greater engagement with treatment and services (MacBeth, Gumley, Schwannauer, & Fisher, 2013). It may be postulated that if service users understand their disorder and treatment then they are more likely to engage in the treatment process.

There was a weak signal (marginally significant) that self-stigma predicted reasoning, while there was no effect of recovery contributing to reasoning capacity. If replicated in a larger sample, this suggests that service users with lower levels of self-stigma may be more able to make comparisons between alternative treatment options by weighing up their consequences, including making inferences about how different treatment options may affect their everyday life, in order to make a treatment decision. On the contrary, for service users with greater self-stigma, this finding may reflect a 'why try' effect (Corrigan et al., 2009) whereby they believe that their diagnosis means that they are not capable of achieving meaningful outcomes, undermining their sense of agency, and preventing them from taking an active role in conceptualising the possible benefits and risks of treatment choices on their everyday lives in order to make a treatment decision. Indeed, service users with moderate levels of self-stigma and good awareness of their disorder were found to

have increased hopelessness and negative expectations of the future, presenting a challenge to their motivation to pursue treatment or recovery goals (Lysaker, Roe & Yanos, 2007). Lysaker, Campbell, & Johannesen (2005) found that when good insight into disorder was accompanied by hopelessness, service users tended to adopt an avoidant coping style, were less inclined to use problem solving, and were more preoccupied with internal distress.

There are several study limitations. Firstly, the study was underpowered, raising the possibility of Type II errors. That said, the correlational analyses demonstrated large effect sizes, thus guiding the decision to perform exploratory regression analyses. However, the regression analyses were likely underpowered to detect significant effects. This was linked to challenges encountered with study recruitment, with a limited number of potential participants meeting diagnostic criteria in the rural population from which the study recruited, and rates for participation in research known to be low for the psychosis population (Honeyman,, 2014; MacBeth et al., 2015). The difficulties with recruitment were unfortunate given the high rate of informed consent following the information session with the researcher and the lack of attrition, indicating that the study had a high acceptability with service users. In light of these difficulties, another limitation of the study was that levels of psychopathology and self-stigma in the sample were low to moderate, which may not be representative of the psychosis population and could limit the generalisability of the findings.

A further limitation was the lack of significant associations found between any of the decisional capacity domains and personal recovery. The MacCAT-T is the gold standard instrument currently available for assessing decisional capacity. The instrument was designed to detect impairment across four domains of decisional

capacity which were developed from a legal framework of competence to give or refuse informed consent (Grisso & Appelbaum, 1998). Previous studies have used the MacCAT-T to measure decisional capacity in psychiatric inpatients where involuntary admissions to hospital are common and a judgement of incapacity is more likely (Okai et al., 2007; Owen et al., 2009). The participants in the current study had only low to moderate levels of psychopathology and mean scores on the four decisional capacity domains were higher than has been found for psychiatric inpatients (Appelbaum, Grisso, & Hill-Fotouhi, 1997). It is possible that the findings in the current study were vulnerable to a floor effect whereby the MacCAT-T instrument was not sensitive to detect changes for participants who did not have impaired capacity. Furthermore, given that the MacCAT-T was operationalised and developed for use within a legal context, it is likely to lack precision within psychological research to detect significant relationships with complex variables such as self-stigma and personal recovery. It has been pointed out previously that the legal conceptualisation of decisional capacity neglects the influence of psychological and environmental factors on decision-making (Stovell et al., 2016). There is a need for a new measure that will partial out effects of cognitive competence, and broaden the construct of capacity to give consideration to the psychosocial context of treatment decision-making.

With regard to clinical application, our findings support emotion-focused conceptualisations of psychosis, highlighting the role of emotion and negative symptoms as predictors of either chronicity or resilience (Freeman & Garety, 2003; Gumley, Gillham, Taylor, & Schwannauer, 2013; Smith et al., 2006). It has been pointed out that trials of cognitive behavioural therapy for psychosis have not directly targeted depression as a primary outcome (Upthegrove et al., 2016). The finding that self-stigma was not significantly associated with positive symptoms suggests

that current psychological interventions based on single-symptom models of positive symptoms may not go far enough to mitigate the effects of self-stigma on emotional distress and personal recovery. However, our findings suggest that adapting these models to target self-stigma may be beneficial. Indeed, a recent pilot randomised controlled trial found that adapting cognitive therapy to address self-stigmatising beliefs produced significant improvement on personal recovery and depression outcomes at post-treatment compared to treatment as usual (Morrison et al., 2016). Furthermore, the change from pre-post treatment indicated large effects (d=1.33) of the intervention on improving personal recovery. As this was a pilot trial, the findings should be replicated with a larger sample, but these early findings are promising.

Consideration of the study findings within the wider empirical literature raises implications for services, and highlights the role of the mental health system in potentially contributing to or counteracting the effects of self-stigma on psychosis. Within current practice, access to mental health care often involves service users being ascribed a clinical diagnosis, however this seems to inadvertently compound the stigmatising stereotypes of psychosis and activates self-stigmatising beliefs. Empirical research into first episode psychosis highlights that individuals are required to access services in the context of interpersonal threat and high emotion (Birchwood et al., 2006; Iqbal et al., 2000) and are likely to delay help-seeking as a safety strategy (Clement et al., 2015). However, this may give rise to compulsory or coercive treatment which is likely to compromise personal recovery. It is therefore important that service providers work with service users to tackle the effects of stigma. One suggestion to mitigate the effects of self-stigma arising from clinical diagnosis is a move away from a diagnostic classification system towards a dimensional approach that understands mental health difficulties as occurring on a

continuum of normal experience (Corrigan, 2007). A move away from clinical diagnosis would counteract the risk of service users being viewed as diagnostic groups, and would promote a holistic, person-centred approach to understanding service users' difficulties (Corrigan, 2007). Adopting a personal recovery model to care could also protect against self-stigma, with mental health professionals communicating messages of hope and recovery, as opposed to the traditional psychiatric view that people with psychosis do not recover (Corrigan, 2007). Offering interventions that directly target self-stigma are likely to alleviate emotional distress and promote adaptation to illness. Furthermore, it has been hypothesised that negative appraisals and emotional difficulties could be trait markers of underlying vulnerability related to social adversity and trauma (Upthegrove et al., 2016). Therefore, therapeutic approaches that address the developmental, emotional and interpersonal processes underpinning the difficulties experienced in psychosis may help to address the challenges of help-seeking and maintain service engagement (Gumley et al., 2013).

In summary, mental health services have tended to focus on indices of clinical recovery, such as managing psychotic symptoms and reducing risk, as the target of treatment (Schrank & Slade, 2007). However, our findings highlight the need for recovery-focused interventions to incorporate consideration of emotion related appraisals, and provide support for service user definitions of recovery which highlight that the psychological and social consequences of having a diagnosis can be more detrimental than the symptoms of the illness itself (Leamy et al., 2011). The cross-sectional design of the current study limits conclusions being drawn about the direction of the relationship between self-stigma and emotional distress. However, it could be that higher endorsement of self-stigmatising beliefs leads to greater levels of distress, or that increased levels of emotional distress make it more

difficult for service users to dismiss negative stereotypes. Longitudinal studies are needed to explore these hypotheses, but in either case, the strong relationship between these variables supports the argument for clinical interventions to go beyond treating the symptoms of illness in order to promote recovery.

There is a consistent pattern emerging from service user research to suggest that overcoming stigma, having hope for the future and becoming empowered to make one's own life choices, including those concerning treatment, are integral processes of the personal recovery journey (Law & Morrison, 2014; Leamy et al., 2011; Schrank & Slade, 2007). The Mental Welfare Commission has endorsed a move towards greater patient involvement in decisions about care and treatment through 'supported decision-making' (Mental Welfare Commission, 2016). However, negative expectations about one's capabilities and worth arising from self-stigmatising beliefs are likely to prevent individuals becoming actively involved in treatment planning. Indeed, empowerment and self-stigma have been conceptualised as belonging to opposite ends of a continuum (Corrigan, 2002; Corrigan, Bink, Schmidt, Jones, & Rüsch, 2015). It has been argued that not involving service users in treatment is likely to reinforce these negative expectations and sense of hopelessness (Corrigan, 2002), compounding the problem. Taken with the findings of the current study, this indicates that interventions that aim to challenge stigmatising beliefs and support personal empowerment are likely to enhance service user engagement and promote recovery. However, further research is needed to provide a clearer picture of the psychosocial influences that may promote or hinder treatment engagement, and a fit-for purpose measure of decisional capacity needs to be developed.

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Appendix 1 – Author guidelines for *Psychology and Psychotherapy: Research, Theory and Practice*

Psychology and Psychotherapy: Theory Research and Practice (formerly The British Journal of Medical Psychology) is an international scientific journal with a focus on the psychological aspects of mental health difficulties and well-being; and psychological problems and their psychological treatments. We welcome submissions from mental health professionals and researchers from all relevant professional backgrounds. The Journal welcomes submissions of original high quality empirical research and rigorous theoretical papers of any theoretical provenance provided they have a bearing upon vulnerability to, adjustment to, assessment of, and recovery (assisted or otherwise) from psychological disorders. Submission of systematic reviews and other research reports which support evidence-based practice are also welcomed, as are relevant high quality analogue studies. The Journal thus aims to promote theoretical and research developments in the understanding of cognitive and emotional factors in psychological disorders, interpersonal attitudes, behaviour and relationships, and psychological therapies (including both process and outcome research) where mental health is concerned. Clinical or case studies will not normally be considered except where they illustrate particularly unusual forms of psychopathology or innovative forms of therapy and meet scientific criteria through appropriate use of single case experimental designs.

All papers published in Psychology and Psychotherapy: Theory, Research and Practice are eligible for Panel A: Psychology, Psychiatry and Neuroscience in the Research Excellence Framework (REF).

1. Circulation

The circulation of the Journal is worldwide. Papers are invited and encouraged from authors throughout the world.

2. Length

All articles submitted to PAPT must adhere to the stated word limit for the particular article type. The journal operates a policy of returning any papers that are over this word limit to the authors. The word limit does not include the abstract, reference list, figures and tables. Appendices however are included in the word limit. The Editors retain discretion to publish papers beyond this length in cases where the clear and concise expression of the scientific content requires greater length (e.g., a new theory or a new method). The authors should contact the Editors first in such a case.

Word limits for specific article types are as follows:

- Research articles: 5000 words
- Qualitative papers: 6000 words
- Review papers: 6000 words
- Special Issue papers: 5000 words

3. Brief reports

These should be limited to 1000 words and may include research studies and theoretical, critical or review comments whose essential contribution can be made briefly. A summary of not more than 50 words should be provided.

4. Submission and reviewing

All manuscripts must be submitted via Editorial Manager. The Journal operates a policy of anonymous (double blind) peer review. We also operate a triage process in which submissions that are out of scope or otherwise inappropriate will be rejected by the editors without external peer review to avoid unnecessary delays. Before submitting, please read the terms and conditions of submission and the declaration of competing interests. You may also like to use the Submission Checklist to help you prepare your paper.

5. Manuscript requirements

• Contributions must be typed in double spacing with wide margins. All sheets must be numbered.

• Manuscripts should be preceded by a title page which includes a full list of authors and their affiliations, as well as the corresponding author's contact details. A template can be downloaded here.

• The main document must be anonymous. Please do not mention the authors' names or affiliations (including in the Method section) and refer to any previous work in the third person.

• Tables should be typed in double spacing, each on a separate page with a self-explanatory title. Tables should be comprehensible without reference to the text. They should be placed at the end of the manuscript but they must be mentioned in the text.

• Figures can be included at the end of the document or attached as separate files, carefully labelled in initial capital/lower case lettering with symbols in a form consistent with text use. Unnecessary background patterns, lines and shading should be avoided. Captions should be listed on a separate sheet. The resolution of digital images must be at least 300 dpi. All figures must be mentioned in the text.

• For articles containing original scientific research, a structured abstract of up to 250 words should be included with the headings: Objectives, Design, Methods, Results, Conclusions. Review articles should use these headings: Purpose, Methods, Results, Conclusions.

• All Articles must include Practitioner Points – these are 2-4 bullet points, in addition to the abstract, with the heading 'Practitioner Points'. These should briefly and clearly outline the relevance of your research to professional practice.

• For reference citations, please use APA style. Particular care should be taken to ensure that references are accurate and complete. Give all journal titles in full and provide DOI numbers where possible for journal articles.

• SI units must be used for all measurements, rounded off to practical values if appropriate, with the imperial equivalent in parentheses.

• In normal circumstances, effect size should be incorporated.

• Authors are requested to avoid the use of sexist language.

• Authors are responsible for acquiring written permission to publish lengthy quotations, illustrations, etc. for which they do not own copyright.

• Manuscripts describing clinical trials must be submitted in accordance with the CONSORT statement on reporting randomised controlled trials (http://www.consort-statement.org).
• Manuscripts describing systematic reviews and meta-analyses must be submitted in accordance with the PRISMA statement on reporting systematic reviews and meta-analyses (http://www.prisma-statement.org).
For guidelines on editorial style, please consult the APA Publication Manual published by the American Psychological Association.
6. Multiple or Linked submissions

Authors considering submitting two or more linked submissions should discuss this with the Editors in the first instance.

7. Supporting Information

PAPT is happy to accept articles with supporting information supplied for online only publication. This may include appendices, supplementary figures, sound files, videoclips etc. These will be posted on Wiley Online Library with the article. The print version will have a note indicating that extra material is available online. Please indicate clearly on submission which material is for online only publication. Please note that extra online only material is published as supplied by the author in the same file format and is not copyedited or typeset. Further information about this service can be found athttp://authorservices.wiley.com/bauthor/suppmat.asp
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If you select the OnlineOpen option and your research is funded by The Wellcome Trust and members of the Research Councils UK (RCUK) or Austrian Science Fund (FWF) you will be given the opportunity to publish your article under a CC-BY license supporting you in complying with your Funder requirements. For more information on this policy and the Journal's compliant self-archiving policy please visit our Funder Policy page.
9. Colour illustrations

Colour illustrations can be accepted for publication online. These would be reproduced in greyscale in the print version. If authors would like these figures to be reproduced in colour in print at their expense they should request this by completing a Colour Work Agreement form upon acceptance of the paper. A copy of the Colour Work Agreement form can be downloaded **here**.

10. Pre-submission English-language editing

Authors for whom English is a second language may choose to have their manuscript professionally edited before submission to improve the English. A list of independent suppliers of editing services can be found athttp://authorservices.wiley.com/bauthor/english_language.asp. All services are paid for and arranged by the author, and use of one of these services does not guarantee acceptance or preference for publication.

11. OnlineOpen

OnlineOpen is available to authors of primary research articles who wish to make their article available to non-subscribers on publication, or whose funding agency requires grantees to archive the final version of their article. With OnlineOpen, the author, the author's funding agency, or the author's institution pays a fee to ensure that the article is made available to non-subscribers upon publication via Wiley Online Library, as well as deposited in the funding agency's preferred archive. For the full list of terms and conditions, see http://wileyonlinelibrary.com/onlineopen#OnlineOpen_Terms
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Prior to acceptance there is no requirement to inform an Editorial Office that you intend to publish your paper OnlineOpen if you do not wish to. All OnlineOpen articles are treated in the same way as any other article. They go through the journal's standard peer-review process and will be accepted or rejected based on their own merit.

12. Author Services

Author Services enables authors to track their article – once it has been accepted – through the production process to publication online and in print. Authors can check the status of their articles online and choose to receive automated e-mails at key stages of production. The author will receive an e-mail with a unique link that enables them to register and have their article automatically added to the system. Please ensure that a complete e-mail address is provided when submitting the manuscript.
Visithttp://authorservices.wiley.com/bauthor/ for more details on online production tracking and for a wealth of resources including FAQs and tips on article preparation, submission and more.

13. The Later Stages

The corresponding author will receive an email alert containing a link to a web site. A working e-mail address must therefore be provided for the corresponding author. The proof can be downloaded as a PDF (portable document format) file from this site. Acrobat Reader will be required in order to read this file. This software can be downloaded (free of charge) from the following web site:http://www.adobe.com/products/acrobat/readstep2.html. This will enable the file to be opened, read on screen and annotated direct in the PDF. Corrections can also be

supplied by hard copy if preferred. Further instructions will be sent with the proof. Hard copy proofs will be posted if no e-mail address is available. Excessive changes made by the author in the proofs, excluding typesetting errors, will be charged separately.

14. Early View

Psychology and Psychotherapy is covered by the Early View service on Wiley Online Library. Early View articles are complete full-text articles published online in advance of their publication in a printed issue. Articles are therefore available as soon as they are ready, rather than having to wait for the next scheduled print issue. Early View articles are complete and final. They have been fully reviewed, revised and edited for publication, and the authors' final corrections have been incorporated. Because they are in final form, no changes can be made after online publication. The nature of Early View articles means that they do not yet have volume, issue or page numbers, so they cannot be cited in the traditional way. They are cited using their Digital Object Identifier (DOI) with no volume and issue or pagination information. E.g., Jones, A.B. (2010). Human rights Issues. *Human Rights Journal*. Advance online publication. doi:10.1111/j.1467-9299.2010.00300.x

Further information about the process of peer review and production can be found in this document. What happens to my paper?

Appendix 2 – PRISMA Checklist

Section/topic	#	Checklist item	Reported on page #
TITLE			
Title	1	Identify the report as a systematic review, meta-analysis, or both.	6
ABSTRACT			
Structured summary	2	Provide a structured summary including, as applicable: background; objectives; data sources; study eligibility criteria, participants, and interventions; study appraisal and synthesis methods; results; limitations; conclusions and implications of key findings; systematic review registration number.	7
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known.	9-10
Objectives	4	Provide an explicit statement of questions being addressed with reference to participants, interventions, comparisons, outcomes, and study design (PICOS).	11
METHODS			
Protocol and registration	5	Indicate if a review protocol exists, if and where it can be accessed (e.g., Web address), and, if available, provide registration information including registration number.	14
Eligibility criteria	6	Specify study characteristics (e.g., PICOS, length of follow-up) and report characteristics (e.g., years considered, language, publication status) used as criteria for eligibility, giving rationale.	13
Information sources	7	Describe all information sources (e.g., databases with dates of coverage, contact with study authors to identify additional studies) in the search and date last searched.	12
Search	8	Present full electronic search strategy for at least one database, including any limits used, such that it could be repeated.	12
Study selection	9	State the process for selecting studies (i.e., screening, eligibility, included in systematic review, and, if applicable, included in the meta-analysis).	13-15

Data collection process	10	Describe method of data extraction from reports (e.g., piloted forms, independently, in duplicate) and any processes for obtaining and confirming data from investigators.	15
Data items	11	List and define all variables for which data were sought (e.g., PICOS, funding sources) and any assumptions and simplifications made.	15
Risk of bias in individual studies	12	Describe methods used for assessing risk of bias of individual studies (including specification of whether this was done at the study or outcome level), and how this information is to be used in any data synthesis.	16
Summary measures	13	State the principal summary measures (e.g., risk ratio, difference in means).	14
Synthesis of results	14	Describe the methods of handling data and combining results of studies, if done, including measures of consistency (e.g., I^2) for each meta-analysis.	12

Section/topic	#	Checklist item	Reported on page #
Risk of bias across studies	15	Specify any assessment of risk of bias that may affect the cumulative evidence (e.g., publication bias, selective reporting within studies).	44
Additional analyses	16	Describe methods of additional analyses (e.g., sensitivity or subgroup analyses, meta-regression), if done, indicating which were pre-specified.	N/A
RESULTS			
Study selection	17	Give numbers of studies screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally with a flow diagram.	17
Study characteristics	18	For each study, present characteristics for which data were extracted (e.g., study size, PICOS, follow-up period) and provide the citations.	25 - 27
Risk of bias within studies	19	Present data on risk of bias of each study and, if available, any outcome level assessment (see item 12).	44
Results of individual studies	20	For all outcomes considered (benefits or harms), present, for each study: (a) simple summary data for each intervention group (b) effect estimates and confidence intervals, ideally with a forest plot.	30 -31

Synthesis of results	21	Present results of each meta-analysis done, including confidence intervals and measures of consistency.	N/A
Risk of bias across studies	22	Present results of any assessment of risk of bias across studies (see Item 15).	44
Additional analysis	23	Give results of additional analyses, if done (e.g., sensitivity or subgroup analyses, meta-regression [see Item 16]).	41 - 43
DISCUSSION			
Summary of evidence	24	Summarize the main findings including the strength of evidence for each main outcome; consider their relevance to key groups (e.g., healthcare providers, users, and policy makers).	46
Limitations	25	Discuss limitations at study and outcome level (e.g., risk of bias), and at review-level (e.g., incomplete retrieval of identified research, reporting bias).	47 - 48
Conclusions	26	Provide a general interpretation of the results in the context of other evidence, and implications for future research.	50 - 51
FUNDING			
Funding	27	Describe sources of funding for the systematic review and other support (e.g., supply of data); role of funders for the systematic review.	N/A

From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

For more information, visit: **www.prisma-statement.org**.

Appendix 3 – The Cochrane Collaboration Data Collection Form for Intervention Reviews: RCTs

Cochrane [NAME] Group

Data collection form for intervention reviews: RCTs only
Version 3, April 2014 ***Replace or delete all text in pink. Modify as necessary before use.***

This form can be used as a guide for developing your own data extraction form. Sections can be expanded and added, and irrelevant sections can be removed. It is difficult to design a single form that meets the needs of all reviews, so it is important to consider carefully the information you need to collect, and design your form accordingly. Information included on this form should be comprehensive, and may be used in the text of your review, 'Characteristics of included studies' table, risk of bias assessment, and statistical analysis.
Using this form, or an adaptation of it, will help you to meet MECIR standards for collecting and reporting information about studies for your review, and analysing their results (see MECIR standards C43 to C55; R41 to R45).

Notes on using data extraction form:

- Be consistent in the order and style you use to describe the information for each report.
- Record any missing information as unclear or not described, to make it clear that the information was not found in the study report(s), not that you forgot to extract it.
- Include any instructions and decision rules on the data collection form, or in an accompanying document. It is important to practice using the form and give training to any other authors using the form.

Review title or ID	
Study ID *(surname of first author and year first full report of study was published e.g. Smith 2001)*	
Report ID	
Report ID of other reports of this study including errata or retractions	
Notes	

General Information

Date form completed *(dd/mm/yyyy)*	
Name/ID of person extracting data	
Reference citation	
Study author contact details	
Publication type *(e.g. full report, abstract, letter)*	
Notes:	

Study eligibility

Study Characteristics	Eligibility criteria *(Insert inclusion criteria for each characteristic as defined in the Protocol)*	Eligibility criteria met? Yes	No	Unclear	Location in text or source *(pg & ¶/fig/table/other)*
Type of study	Randomised controlled trial	☐	☐	☐	
	Quasi-randomised controlled trial	☐	☐	☐	
Participants		☐	☐	☐	
Types of intervention		☐	☐	☐	
Types of comparison		☐	☐	☐	
Types of outcome measures		☐	☐	☐	
INCLUDE ☐		EXCLUDE ☐			
Reason for exclusion					
Notes:					

DO NOT PROCEED IF STUDY EXCLUDED FROM REVIEW

Characteristics of included studies

Methods

	Descriptions as stated in report/paper	**Location in text or source** *(pg & ¶/fig/table/other)*
Aim of study *(e.g. efficacy, equivalence, pragmatic)*		
Design *(e.g. parallel, crossover, non-RCT)*		

Unit of allocation *(by individuals, cluster/ groups or body parts)*			
Start date			
End date			
Duration of participation *(from recruitment to last follow-up)*			
Ethical approval needed/ obtained for study	☐ Yes ☐ No ☐ Unclear		
Notes:			

Participants

	Description *Include comparative information for each intervention or comparison group if available*	Location in text or source *(pg & ¶/fig/table/other)*
Population description *(from which study participants are drawn)*		
Setting *(including location and social context)*		
Inclusion criteria		
Exclusion criteria		
Method of recruitment of participants *(e.g. phone, mail, clinic patients)*		
Informed consent obtained	☐ Yes ☐ No ☐ Unclear	
Total no. randomised *(or total pop. at start of study for non-RCTs)*		
Clusters *(if applicable, no., type, no. people per cluster)*		
Baseline imbalances		
Withdrawals and exclusions *(if not provided below by outcome)*		
Age		
Sex		
Race/ethnicity		
Severity of illness		
Co-morbidities		
Other relevant sociodemographics		
Subgroups measured		
Subgroups reported		

Intervention groups

Copy and paste table for each intervention and comparison group

Intervention Group 1

	Description as stated in report/paper	Location in text or source *(pg & ¶/fig/table/other)*
Group name		
No. randomised to group *(specify whether no. people or clusters)*		
Theoretical basis *(include key references)*		
Description *(include sufficient detail for replication, e.g. content, dose, components)*		
Duration of treatment period		
Timing *(e.g. frequency, duration of each episode)*		
Delivery *(e.g. mechanism, medium, intensity, fidelity)*		
Providers *(e.g. no., profession, training, ethnicity etc. if relevant)*		
Co-interventions		
Economic information *(i.e. intervention cost, changes in other costs as result of intervention)*		
Resource requirements *(e.g. staff numbers, cold chain, equipment)*		
Integrity of delivery		
Compliance		

Notes:

Outcomes

Copy and paste table for each outcome.

Outcome 1

	Description as stated in report/paper	Location in text or source *(pg & ¶/fig/table/other)*
Outcome name		
Time points measured *(specify whether from start or end of intervention)*		
Time points reported		
Outcome definition *(with diagnostic criteria if relevant)*		
Person measuring/ reporting		
Unit of measurement *(if relevant)*		
Scales: upper and lower limits *(indicate whether high or low score is good)*		
Is outcome/tool validated?	☐ Yes ☐ No ☐ Unclear	
Imputation of missing data *(e.g. assumptions made for ITT analysis)*		
Assumed risk estimate *(e.g. baseline or population risk noted in Background)*		

Power *(e.g. power & sample size calculation, level of power achieved)*		

Risk of Bias assessment

(See Handbook Chapter 8. Additional domains may be added for non-randomised studies.)

Domain	Risk of bias Low High Unclear	Support for judgement *(include direct quotes where available with explanatory comments)*	Location in text or source *(pg & ¶/fig/table/other)*
Random sequence generation *(selection bias)*	☐ ☐ ☐		
Allocation concealment *(selection bias)*	☐ ☐ ☐		
Blinding of participants and personnel *(performance bias)*	☐ ☐ ☐	Outcome group: All/	
(if separate judgement by outcome(s) required)	☐ ☐ ☐	Outcome group:	
Blinding of outcome assessment *(detection bias)*	☐ ☐ ☐	Outcome group: All/	
(if separate judgement by outcome(s) required)	☐ ☐ ☐	Outcome group:	
Incomplete outcome data *(attrition bias)*	☐ ☐ ☐	Outcome group: All/	

(if separate judgement by outcome(s) required)	☐ ☐ ☐	Outcome group:	
Selective outcome reporting? *(reporting bias)*	☐ ☐ ☐		
Other bias	☐ ☐ ☐		
Notes:			

Data and analysis

Copy and paste the appropriate table for each outcome, including additional tables for each time point and subgroup as required.

Dichotomous outcome

	Description as stated in report/paper				Location in text or source *(pg & ¶/fig/table/other)*
Comparison					
Outcome					
Subgroup					
Time point *(specify from start or end of intervention)*					
Results	Intervention		Comparison		
	No. with event	Total in group	No. with event	Total in group	
Any other results reported *(e.g. odds ratio, risk difference, CI or P value)*					
No. missing participants					
Reasons missing					
No. participants moved from other group					
Reasons moved					

Unit of analysis *(by individuals, cluster/groups or body parts)*			
Statistical methods used and appropriateness of these *(e.g. adjustment for correlation)*			
Reanalysis required? *(specify, e.g. correlation adjustment)*	☐ Yes ☐ No ☐ Unclear		
Reanalysis possible?	☐ Yes ☐ No ☐ Unclear		
Reanalysed results			
Notes:			

Continuous outcome

	Description as stated in report/paper	Location in text or source *(pg & ¶/fig/table/other)*
Comparison		
Outcome		
Subgroup		
Time point *(specify from start or end of intervention)*		
Post-intervention or change from baseline?		

Results	Intervention			Comparison			
	Mean	SD *(or other variance, specify)*	No. participants	Mean	SD *(or other variance, specify)*	No. participants	

Any other results reported *(e.g. mean difference, CI, P value)*			
No. missing participants			
Reasons missing			
No. participants moved from other group			
Reasons moved			
Unit of analysis *(individuals, cluster/ groups or body parts)*			
Statistical methods used and appropriateness of these *(e.g. adjustment for correlation)*			
Reanalysis required? *(specify)*	☐ Yes ☐ No ☐ Unclear		
Reanalysis possible?	☐ Yes ☐ No ☐ Unclear		
Reanalysed results			
Notes:			

Other outcome

	Description as stated in report/paper	Location in text or source *(pg & ¶/fig/table/other)*
Comparison		

Outcome					
Subgroup					
Time point *(specify from start or end of intervention)*					
No. participant	Intervention		Control		
Results	Intervention result	SE (or other variance)	Control result	SE (or other variance)	
	Overall results		SE (or other variance)		
Any other results reported					
No. missing participants					
Reasons missing					
No. participants moved from other group					
Reasons moved					
Unit of analysis *(by individuals, cluster/groups or body parts)*					
Statistical methods used and appropriateness of these					
Reanalysis required? *(specify)*	☐ Yes ☐ No ☐ Unclear				
Reanalysis possible?	☐ Yes ☐ No ☐ Unclear				
Reanalysed results					

Other information

	Description as stated in report/paper	Location in text or source *(pg & ¶/fig/table/other)*
Key conclusions of study authors		
References to other relevant studies		
Correspondence required for further study information *(from whom, what and when)*		
Notes:		

Definitions

Assumed risk estimate	An estimate of the risk of an event or average score without the intervention, used in Cochrane 'Summary of findings tables'. If a study provides useful estimates of the risk or average score of different subgroups of the population, or an estimate based on a representative observational study, you may wish to collect this information.
Bias	A systematic error or deviation in results or inferences from the truth. In studies of the effects of health care, the main types of bias arise from systematic differences in the groups that are compared (selection bias), the care that is provided, exposure to other factors apart from the intervention of interest (performance bias), withdrawals or exclusions of people entered into a study (attrition bias) or how outcomes are assessed (detection bias). Reviews of studies may also be particularly affected by reporting bias, where a biased subset of all the relevant data is available.
Change from baseline	A measure for a continuous outcome calculated as the difference between the baseline score and the post-intervention score.
Clusters	A group of participants who have been allocated to the same intervention arm together, as in a cluster-randomised trial, e.g. a whole family, town, school or patients in a clinic may be allocated to the same intervention rather than separately allocating each individual to different arms.
Co-morbidities	The presence of one or more diseases or conditions other than those of primary interest. In a study looking at treatment for one disease or condition, some of the individuals may have other diseases or conditions that could affect their outcomes.
Compliance	Participant behaviour that abides by the recommendations of a doctor, other health care provider or study investigator (also called adherence or concordance).

Contemporaneous data collection	When data are collected at the same point(s) in time or covering the same time period for each intervention arm in a study (that is, historical data are not used as a comparison).
Controlled Before and After Study (CBA)	A non-randomised study design where a control population of similar characteristics and performance as the intervention group is identified. Data are collected before and after the intervention in both the control and intervention groups
Exclusions	Participants who were excluded from the study or the analysis by the investigators.
Imputation	Assuming a value for a measure where the true value is not available (e.g. assuming last observation carried forward for missing participants).
Integrity of delivery	The degree to which the specified procedures or components of an intervention are delivered as originally planned.
Interrupted Time Series (ITS)	A research design that collects observations at multiple time points before and after an intervention (interruption). The design attempts to detect whether the intervention has had an effect significantly greater than the underlying trend.
Post-intervention	The value of an outcome measured at some time point following the beginning of the intervention (may be during or after the intervention period).
Power	In clinical trials, power is the probability that a trial will obtain a statistically significant result when the true intervention effect is a specified size. For a given size of effect, studies with more participants have greater power. Note that power should not be considered in the risk of bias assessment.
Providers	The person or people responsible for delivering an intervention and related care, who may or may not require specific qualifications (e.g. doctors, physiotherapists) or training.

Quasi-randomised controlled trial	A study in which the method of allocating people to intervention arms was not random, but was intended to produce similar groups when used to allocate participants. Quasi-random methods include: allocation by the person's date of birth, by the day of the week or month of the year, by a person's medical record number, or just allocating every alternate person.
Reanalysis	Additional analysis of a study's results by a review author (e.g. to introduce adjustment for correlation that was not done by the study authors).
Report ID	A unique ID code given to a publication or other report of a study by the review author (e.g. first author's name and year of publication). If a study has more than one report (e.g. multiple publications or additional unpublished data) a separate Report ID can be allocated to each to help review authors keep track of the source of extracted data.
Sociodemographics	Social and demographic information about a study or its participants, including economic and cultural information, location, age, gender, ethnicity, etc.
Study ID	A unique ID code given to an included or excluded study by the review author (e.g. first author's name and year of publication from the main report of the study). Although a study may have multiple reports or references, it should have one single Study ID to help review authors keep track of all the different sources of information for a study.
Theoretical basis	The use of a particular theory (such as theories of human behaviour change) to design the components and implementation of an intervention
Unit of allocation	The unit allocated to an intervention arm. In most studies individual participants will be allocated, but in others it may be individual body parts (e.g. different teeth or joints may be allocated separately) or clusters of multiple people.

Unit of analysis	The unit used to calculate N in an analysis, and for which the result is reported. This may be the number of individual people, or the number of body parts or clusters of people in the study.
Unit of measurement	The unit in which an outcome is measured, e.g. height may be measured in cm or inches; depression may be measured using points on a particular scale.
Validation	A process to test and establish that a particular measurement tool or scale is a good measure of that outcome.
Withdrawals	Participants who voluntarily withdrew from participation in a study before the completion of outcome measurement.

Sources:

Cochrane Collaboration Glossary, 2010. Available from www.cochrane.org/glossary.
Higgins JPT, Green S (editors). Cochrane Handbook for Systematic Reviews of Interventions Version 5.1.0 [updated March 2011]. The Cochrane Collaboration, 2011. Available from handbook.cochrane.org.
Last JM (editor), A Dictionary of Epidemiology, 4th Ed. New York: Oxford University Press, 2001.
Schünemann H, Brożek J, Oxman A, editors. GRADE handbook for grading quality of evidence and strength of recommendation. Version 3.2 [updated March 2009)

Appendix 4 - Reasons for studies excluded (n=119) following full-text review

	Authors	Year	Reason for exclusion
1	Ahmed, AO; Hunter, KM; Goodrum, NM; Batten, NJ; Birgenheir, D; Hardison, E; Dixon, T; Buckley, PF	2015	Personal recovery measure not relevant
2	Au, DWH; Tsang, HWH; So, WWY; Bell, MD; Cheung, V; Yiu, MGC; Tam, KL; Lee, GTH	2015	Intervention not relevant/personal recovery not an outcome
3	Bartels, SJ; Pratt, SI; Mueser, KT; Naslund, JA; Wolfe, RS; Santos, M; Xie, HY; Riera, EG	2014	Less than 50% with psychosis/personal recovery not an outcome
4	Barton, GR; Hodgekins, J; Mugford, M; Jones, PB; Croudace, T; Fowler, D	2009	Secondary analysis of RCT/personal recovery not an outcome
5	Bechdolf, A; Kohn, D; Knost, B; Pukrop, R; Klosterkotter, J	2005	Personal recovery not an outcome
6	Beentjes, TAA; van Gaal, BGI; Goossens, PJJ; Schoonhoven, L	2016	Study protocol/personal recovery measure not relevant
7	Bertelsen et al. (2009)	2009	Personal recovery not an outcome
8	Bitter, NA; Roeg, DPK; van Nieuwenhuizen, C; van Weeghel, J	2015	Study protocol/personal recovery measure not relevant (MHRM)
9	Bower, P; Roberts, C; O'Leary, N; Callaghan, P; Bee, P; Fraser, C; Gibbons, C; Olleveant, N; Rogers, A; Davies, L; Drake, R; Sanders, C; Meade, O; Grundy, A; Walker, L; Cree, L; Berzins, K; Brooks, H; Beatty, S; Cahoon, P; Rolfe, A; Lovell, K	2015	Study protocol/personal recovery not an outcome (recovery orientation DREEM measure)
10	Braehler, C; Gumley, A; Harper, J; Wallace, S; Norrie, J; Gilbert, P	2013	Personal recovery not an outcome
11	Cai, CF; Yu, LP; Rong, L; Zhong, HL	2014	Personal recovery not an outcome
12	Cather, C; Penn, D; Otto, MW; Yovel, I; Mueser, KT; Goff, DC	2005	Personal recovery not an outcome
13	Chadwick, Paul	2016	Personal recovery not an outcome
14	Chan, SWC; Li, ZQ; Klainin-Yobas, P; Ting, S; Chan, MF; Eu, PW	2014	Study protocol/would be eligible
15	Chinman, M; Oberman, RS; Hanusa, BH; Cohen, AN; Salyers, MP; Twamley, EW; Young, AS	2015	Personal recovery measure not relevant (MHRM & IMR)
16	Compton, MT; Kelley, ME; Pope, A; Smith, K; Broussard, B; Reed, TA; DiPolito, JA; Druss, BG; Li, C; Haynes, NL	2016	Not RCT/personal recovery measure not relevant (MHRM)

17	Cook, JA; Copeland, ME; Floyd, CB; Jonikas, JA; Hamilton, MM; Razzano, L; Carter, TM; Hudson, WB; Grey, DD; Boyd, S	2012	Less than 50% with psychosis
18	Cook, JA; Copeland, ME; Jonikas, JA; Hamilton, MM; Razzano, LA; Grey, DD; Floyd, CB; Hudson, WB; Macfarlane, RT; Carter, TM; Boyd, S	2012	Personal recovery not an outcome
19	Cook, JA; Jonikas, JA; Hamilton, MM; Goldrick, V; Steigman, PJ; Grey, DD; Burke, L; Carter, TM; Razzano, LA; Copeland, ME	2013	Fewer than 50% with psychosis
20	Cook, JA; Steigman, P; Pickett, S; Diehl, S; Fox, A; Shipley, P; MacFarlane, R; Grey, DD; Burke-Miller, JK	2012	Fewer than 50% with psychosis
21	Cook, S; Chambers, E; Coleman, JH	2009	Personal recovery not an outcome
22	Dalum, HS; Korsbek, L; Mikkelsen, JH; Thomsen, K; Kistrup, K; Olander, M; Hansen, JL; Nordentoft, M; Eplov, LF	2011	Study protocol/personal recovery measure not relevant (IMR & MHRM)
23	Davis, LW; Lysaker, PH; Kristeller, JL; Salyers, MP; Kovach, AC; Woller, S	2015	Personal recovery not an outcome
24	De Jong et al. (2013)	2013	Study protocol/personal recovery not an outcome
25	Deane, FP; Marshall, S; Crowe, T; White, A; Kavanagh, D	2015	Intervention not relevant/personal recovery not an outcome
26	Dixon et al.	2014	Personal recovery measure not relevant (MHRM)
27	Dixon, LB; Goldman, HH; Bennett, ME; Wang, YJ; McNamara, KA; Mendon, SJ; Goldstein, AB; Choi, CWJ; Lee, RJ; Lieberman, JA; Essock, SM	2015	Not RCT/Personal recovery not an outcome
28	Drury et al. (1996)	1996	Personal recovery not an outcome
29	Drury et al. (1996)	1996	Personal recovery not an outcome
30	Drury, V; Birchwood, M; Cochrane, R	2000	Personal recovery not an outcome
31	Eack, SM; Hogarty, GE; Greenwald, DP; Hogarty, SS; Keshavan, MS	2011	Personal recovery not an outcome
32	Eisen et al. (2012)	2012	Less than 50% with psychosis
33	Fowler et al. (2009)	2009	Personal recovery not an outcome
34	Fowler, D; Hodgekins, J; Howells, L; Millward, M; Ivins, A; Taylor, G; Hackmann, C; Hill, K; Bishop, N; Macmillan, I	2009	Not RCT/personal recovery not an outcome
35	Fowler, D; Hodgekins, J; Painter, M; Reilly, T; Crane, C; Macmillan, I; Mugford, M; Croudace, T; Jones, PB	2009	Personal recovery not an outcome

36	Freeman et al. (2016)	2016	Study protocol/personal recovery not an outcome
37	Freeman, D; Waite, F; Emsley, R; Kingdon, D; Davies, L; Fitzpatrick, R; Dunn, G	2016	Study protocol/personal recovery not an outcome
38	Fung, KMT; Tsang, HWH; Cheung, WM	2011	Personal recovery not an outcome
39	Galderisi, S; Piegari, G; Mucci, A; Acerra, A; Luciano, L; Rabasca, AF; Santucci, F; Valente, A; Volpe, M; Mastantuono, P; Maj, M	2010	Personal recovery not an outcome
40	Goldberg, JO; Wheeler, H; Lubinsky, T; Van Exan, J	2007	Not RCT/personal recovery not an outcome
41	Grant, PM; Huh, GA; Perivoliotis, D; Stolar, NM; Beck, AT	2012	Personal recovery not an outcome
42	Haddock, G; Tarrier, N; Morrison, AP; Hopkins, R; Drake, R; Lewis, S	1999	Personal recovery not an outcome
43	Hasson-Ohayon, I; Roe, D; Kravetz, S	2007	Personal recovery measure not relevant (IMRS)
44	Hodgekins, J; Fowler, D	2010	Secondary analysis of RCT
45	Hoffmann, H; Jackel, D; Glauser, S; Mueser, KT; Kupper, Z	2014	Intervention not relevant/personal recovery not an outcome (recovery attitudes measured with RPI)
46	Hogarty, GE; Flesher, S; Ulrich, R; Carter, M; Greenwald, D; Pogue-Geile, M; Kechavan, M; Cooley, S; DiBarry, AL; Garrett, A; Parepally, H; Zoretich, R	2004	Personal recovery not an outcome
47	Jackson, C; Trower, P; Reid, I; Smith, J; Hall, M; Townend, M; Barton, K; Jones, J; Ross, K; Russell, R; Newton, E; Dunn, G; Birchwood, M	2009	Personal recovery not an outcome
48	Jackson, H; McGorry, P; Edwards, J; Hulbert, C; Henry, L; Francey, S; Maude, D; Cocks, J; Power, P; Harrigan, S; Dudgeon, P	1998	Personal recovery not an outcome
49	Jackson, H; McGorry, P; Edwards, J; Hulbert, C; Henry, L; Harrigan, S; Dudgeon, P; Francey, S; Maude, D; Cocks, J; Killackey, E; Power, P	2005	Personal recovery not an outcome
50	Jackson, H; McGorry, P; Henry, L; Edwards, J; Hulbert, C; Harrigan, S; Dudgeon, P; Francey, S; Maude, D; Cocks, J; Power, P	2001	Personal recovery not an outcome
51	Jackson, HJ; McGorry, PD; Killackey, E; Bendall, S; Allott, K; Dudgeon, P; Gleeson, J; Johnson, T; Harrigan, S	2008	Personal recovery not an outcome
52	Jolley et al. (2003)	2003	Personal recovery not an outcome

53	Jonikas, JA; Grey, DD; Copeland, ME; Razzano, LA; Hamilton, MM; Floyd, CB; Hudson, WB; Cook, JA	2013	Personal recovery not an outcome
54	Kaplan, K; Salzer, MS; Solomon, P; Brusilovskiy, E; Cousounis, P	2011	Fewer than 50% with psychosis
55	Killaspy, H; Cook, S; Mundy, T; Craig, T; Holloway, F; Leavey, G; Marston, L; McCrone, P; Koeser, L; Arbuthnott, M; Omar, RZ; King, M	2013	Study protocol/personal recovery not an outcome
56	Koike, S; Nishida, A; Yamasaki, S; Ichihashi, K; Maegawa, S; Natsubori, T; Harima, H; Kasai, K; Fujita, I; Harada, M; Okazaki, Y	2011	Study protocol/personal recovery not an outcome
57	Korsbek, L; Tonder, ES	2016	Qualitative study
58	Kuipers, E; Fowler, D; Garety, P; Chisholm, D; Freeman, D; Dunn, G; Bebbington, P; Hadley, C	1998	Personal recovery not an outcome
59	Lee, CC; Ip, G; Chu, M; Lo, TL; Ip, YC	2014	Personal recovery not an outcome
60	Lee, CC; Liem, SK; Leung, J; Young, V; Wu, K; Kenny, KKW; Yuen, SK; Lee, WF; Leung, T; Shum, M; Kwong, P; Lo, W	2015	Not RCT/Personal recovery not an outcome
61	Lester, H; Birchwood, M; Freemantle, N; Michail, M; Tait, L	2009	Personal recovery not an outcome
62	Levitt, AJ; Mueser, KT; DeGenova, J; Lorenzo, J; Bradford-Watt, D; Barbosa, A; Karlin, M; Chernick, M	2009	Personal recovery measure not relevant (IMRS)
63	Lewis, S; Tarrier, N; Haddock, G; Bentall, R; Kinderman, P; Kingdon, D; Siddle, R; Drake, R; Everitt, J; Leadley, K; Benn, A; Grazebrook, K; Haley, C; Akhtar, S; Davies, L; Palmer, S; Faragher, B; Dunn, G	2002	Personal recovery not an outcome
64	Lin, ECL; Chan, CH; Shao, WC; Lin, MF; Shiau, SJ; Mueser, KT; Huang, SC; Wang, HS	2013	Personal recovery not an outcome
65	Lorig, K; Ritter, PL; Pifer, C; Werner, P	2014	Not RCT/personal recovery not an outcome
66	Lysaker, PH; Davis, LW; Bryson, GJ; Bell, MD	2009	Intervention not relevant/personal recovery not an outcome
67	Mairs, H; Lovell, K; Campbell, M; Keeley, P	2011	Not RCT/personal recovery not an outcome
68	Malik, N; Kingdon, D; Pelton, J; Mehta, R; Turkington, D	2009	Personal recovery not an outcome
69	Malm, U; Ivarsson, B; Allebeck, P; Falloon, IRH	2003	Personal recovery not an outcome
70	Marchinko, S; Clarke, D	2011	Not RCT

71	McGurk, SR; Mueser, KT; DeRosa, TJ; Wolfe, R	2009	Personal recovery not an outcome
72	Michaels, PJ; Corrigan, PW; Buchholz, B; Brown, J; Arthur, T; Netter, C; MacDonald-Wilson, KL	2014	Not non-affective psychosis population - SMI
73	Morrison, AP; Hutton, P; Wardle, M; Spencer, H; Barratt, S; Brabban, A; Callcott, P; Christodoulides, T; Dudley, R; French, P; Lumley, V; Tai, SJ; Turkington, D	2012	Not RCT
74	Morrissey, JP; Domino, ME; Cuddeback, GS	2013	Not RCT/personal recovery not an outcome
75	Mortan, O; Sutcu, ST; Kose, GG	2011	Not RCT/personal recovery not an outcome
76	O'Brien, S; McFarland, J; Kealy, B; Pullela, A; Saunders, J; Cullen, W; Meagher, D	2012	Personal recovery not an outcome/unclear if 50% with psychosis diagnosis - SMI
77	O'Reilly, K; Donohoe, G; O'Sullivan, D; Coyle, C; Mullaney, R; O'Connell, P; Maddock, C; Nulty, A; O'Flynn, P; O'Connell, C; Kennedy, HG	2016	Study protocol/personal recovery not an outcome
78	Palma-Sevillano, C; Canete-Crespillo, J; Farriols-Hernando, N; Cebria-Andreu, J; Michael, M; Alonso-Fernandez, I; Fernandez-Vargas, M; Segarra-Gutierrez, G	2011	Personal recovery not an outcome
79	Palmer, VJ; Chondros, P; Piper, D; Callander, R; Weavell, W; Godbee, K; Potiriadis, M; Richard, L; Densely, K; Herrman, H; Furler, J; Pierce, D; Schuster, T; Iedema, R; Gunn, J	2015	Study protocol/uses RAS-R/not psychosis population - severe mental illness
80	Penn, DL; Uzenoff, SR; Perkins, D; Mueser, KT; Hamer, R; Waldheter, E; Saade, S; Cook, L	2011	Personal recovery not an outcome
81	Pickett, SA; Diehl, S; Steigman, PJ; Prater, JD; Fox, A; Cook, JA	2010	Fewer than 50% with psychosis
82	Pickett, SA; Diehl, SM; Steigman, PJ; Prater, JD; Fox, A; Shipley, P; Grey, DD; Cook, JA	2012	Personal recovery not an outcome
83	Rector, NA; Seeman, MV; Segal, ZV	2003	Personal recovery not an outcome
84	Roe, D; Hasson-Ohayon, I; Mashiach-Eizenberg, M; Derhy, O; Lysaker, PH; Yanos, PT	2014	Not RCT/personal recovery not an outcome/not psychosis population - "psychiatric disability"
85	Roosenschoon B.-J.	2016	Study protocol/personal recovery measure not relevant (MHRM)
86	Ruchlewska et al. (2009)	2009	Personal recovery not an outcome
87	Russinova, Z; Rogers, ES; Gagne, C; Bloch, P; Drake, KM; Mueser, KT	2014	Personal recovery measure not relevant/Not psychosis population - SMI

88	Salyers et al. (2010)	2010	Personal recovery not an outcome
89	Schrank, B; Riches, S; Coggins, T; Rashid, T; Tylee, A; Slade, M	2014	Study protocol/personal recovery not an outcome
90	Segal, SP; Silverman, CJ; Temkin, TL	2011	Personal recovery not an outcome
91	Segal, SP; Silverman, CJ; Temkin, TL	2010	Personal recovery not an outcome
92	Shahar, G; Kidd, S; Styron, TH; Davidson, L	2006	Secondary analysis of RCT/personal recovery not an outcome/50% with "psychotic disorder" may include bipolar
93	Shawyer et al. (2012)	2012	Personal recovery not an outcome
94	Silverman, MJ	2014	No personal recovery measure/less than 50% psychosis
95	Silverstein et al. (2014)	2014	Personal recovery not an outcome
96	Sin, J; Henderson, C; Pinfold, V; Norman, I	2013	Not relevant/personal recovery not an outcome
97	Slade, M; Bird, V; Le Boutillier, C; Williams, J; McCrone, P; Leamy, M	2011	Study protocol
98	Stanhope, V; Tondora, J; Davidson, L; Choy-Brown, M; Marcus, SC	2015	Study protocol/personal recovery not an outcome (RSA is recovery orientation of services)
99	Startup, M; Jackson, MC; Bendix, S	2004	Personal recovery not an outcome
100	Startup, M; Jackson, MC; Startup, S	2006	Personal recovery not an outcome
101	Steigman, PJ; Pickett, SA; Diehl, SM; Fox, A; Grey, DD; Shipley, P; Cook, JA	2014	Personal recovery not an outcome
102	Tarrier et al. (1999)	1999	Personal recovery not an outcome
103	Tarrier, N; Haddock, G; Lewis, S; Drake, R; Gregg, L	2006	Personal recovery not an outcome
104	Tarrier, N; Lewis, S; Haddock, G; Bentall, R; Drake, R; Kinderman, P; Kingdon, D; Siddle, R; Everitt, J; Leadley, K; Benn, A; Grazebrook, K; Haley, C; Akhtar, S; Davies, L; Palmer, S; Dunn, G	2004	Personal recovery not an outcome
105	Tas, C; Danaci, AE; Cubukcuoglu, Z; Brune, M	2012	Personal recovery not an outcome
106	Taylor, R; Cella, M; Csipke, E; Heriot-Maitland, C; Gibbs, C; Wykes, T	2016	Personal recovery not an outcome
107	Tsang, HWH; Ching, SC; Tang, KH; Lam, HT; Law, PYY; Wan, CN	2016	Review
108	Turkington, D; Kingdon, D; Rathod, S; Hammond, K; Pelton, J; Mehta, R	2006	Personal recovery not an outcome
109	Turkington, D; Sensky, T; Scott, J; Barnes, TRE; Nur, U; Siddle,	2008	Personal recovery not an outcome

	R; Hammond, K; Samarasekara, N; Kingdon, D		
110	Uzenoff, SR; Perkins, DO; Hamer, RM; Wiesen, CA; Penn, DL	2008	Personal recovery not an outcome
111	van Gestel-Timmermans, H; Brouwers, EPM; van Assen, MALM; van Nieuwenhuizen, C	2012	Personal recovery not an outcome
112	van Veen, M; Koekkoek, B; Mulder, N; Postulart, D; Adang, E; Teerenstra, S; Schoonhoven, L; van Achterberg, T	2015	Study protocol/psychotic disorders excluded/personal recovery not an outcome (IMR)
113	Velligan, DI; Draper, M; Stutes, D; Maples, N; Mintz, J; Tai, S; Turkington, D	2009	Personal recovery not an outcome
114	Vita, A; De Peri, L; Barlati, S; Cacciani, P; Deste, G; Poli, R; Agrimi, E; Cesana, BM; Sacchetti, E	2011	Personal recovery not an outcome
115	Waldheter, EJ; Penn, DL; Perkins, DO; Mueser, KT; Owens, LW; Cook, E	2008	Not RCT/personal recovery not an outcome
116	Waller, H; Craig, T; Landau, S; Fornells-Ambrojo, M; Hassanali, N; Iredale, C; Jolley, S; McCrone, P; Garety, P	2014	Study protocol/personal recovery not an outcome
117	Wiersma, D; Jenner, JA; Nienhuis, FJ; van de Willige, G	2004	Personal recovery not an outcome
118	Yamada, AM; Lee, KK; Dinh, TQ; Barrio, C; Brekke, JS	2010	Not RCT/personal recovery not an outcome
119	Yanos, PT; Lucksted, A; Drapalski, AL; Roe, D; Lysaker, P	2015	Review/read to identify potential studies

Appendix 5 - Support for risk of bias judgements by rater 1 (HL)

Study 1: Barbic 2009

Domain	Judgement	Support for judgement
Sequence generation	UNCLEAR	Method used to generate the allocation sequence not described in sufficient detail. "...the participants were grouped on the basis of which team they received ACT services from. Next, participants were randomly assigned to either the intervention or control group".
Allocation concealment	UNCLEAR	No description of method to conceal the allocation sequence.
Performance bias (blinding of participants and personnel)	HIGH	All outcomes are self-reported. Participants not blinded and intervention providers not blinded (one study author and another a paid member of ACT team in the study).
Detection bias (blinding of outcome assessment)	UNCLEAR	All outcomes are self-reported (hope, empowerment, personal recovery, and QoL). Participants not blinded, but outcome assessors were blinded. "Study assessments were conducted one week before randomization and within three days of completion of the intervention. Three assessors, who were blind to the treatment condition, conducted assessments of all study groups". Did not report whether or not there were any blind breaks, and no description of any attempts to counter potential blind breaks.
Incomplete outcome data	UNCLEAR	Completeness of outcome data unclear - no exclusions or attrition reported – not clear how many participants/data were lost from the study groups, and what the reasons for missing data were: "In an additional sensitivity analysis, missing values for the primary outcome measures were

		replaced by the median of the sample". "All statistical analyses were intent-to-treat analyses"
Selective outcome reporting	UNCLEAR	All expected outcomes in the methods section are reported as planned, but no pre-registered study protocol.
Other bias	UNCLEAR	81 people identified as meeting study eligibility criteria, but only 33 people (40.7%) agreed to randomisation. No information collected about non-participants.

Study 2: Fardig 2011

Entry	Judgement	Support for judgement
Sequence generation	LOW	" A computerised random number generator was used to assign the 41 participants who completed the baseline assessment and gave informed consent to one of the six IMR program groups" (pg 607)
Allocation concealment	UNCLEAR	No description of method to conceal the allocation sequence.
Performance bias (blinding of participants and personnel)	HIGH	Participants not blinded – intervention group would know they received treatment in addition to TAU. Information given to participants not described. Intervention providers not blinded – clinicians delivering the intervention would know which participants belong to the intervention group.
Detection bias (blinding of outcome assessment)	HIGH	<u>Personnel-measured outcomes</u> Clinician-rated IMRS (illness management): Participants not blinded, assessors not blinded "participants' case managers, who were not blind to treatment assignment, provided ratings on the clinician version of the IMR scale" (pg 607)

	UNCLEAR	PECC (psychiatric symptoms): "assessments of psychiatric symptoms were conducted by trained clinicians who were blind to treatment assignment". Information given to participants not described, but participants in the IMR group likely to be aware they are receiving intervention in addition to TAU - not blinded. Did not report whether or not there were any blind breaks, and no description of any attempts to counter potential blind breaks (e.g. participants disclosing to assessors which group they had been allocated).
	UNCLEAR	Hospitalisations – no information to describe who reviewed medical records so unclear if blinded. Suicidal ideation in the past week – does not say how this was assessed and not clear by whom this was assessed.
	UNCLEAR	<u>Participant-rated outcome measures</u> RAS (41 item)/ MANSA (quality of life)/WCQ (ways of coping) Information given to participants not described, but participants in the IMR group likely to be aware they are receiving intervention in addition to TAU - not blinded. Knowledge of group could influence ratings.
Incomplete outcome data	LOW	All participants completed measures at baseline and posttreatment 19 of the 21 IMR participants completed measures at FU 19 of the 20 TAU participants completed measures at FU Total attrition 7.3% Reasons reported for missing data (1 participant from each group did not respond to a request to schedule the FU assessment, and 1 participant in the IMR group died)
Selective outcome reporting	UNCLEAR	All expected outcomes in the methods section are reported as planned, but no pre-registered study protocol.

Other bias	UNCLEAR	Number of people identified as meeting study eligibility criteria not reported, only the number of participants who gave informed consent to take part (n=41). Authors state in discussion that recruitment of sample was based on convenience.

Study 3: Huguelet 2011

Entry	Judgement	Support for judgement
Sequence generation	LOW	"To ensure random selection, all eligible patients of each psychiatrist were assigned a random number and then listed in numerical order. Up to 14 patients per clinician were selected…. The first seven patients on the numerical list were assigned to the intervention group…. The last seven patients on the list were assigned to the control group, which received only standard treatment"
Allocation concealment	UNCLEAR	No description of method to conceal allocation sequence.
Performance bias (blinding of participants and personnel)	HIGH	Participants and intervention providers (psychiatrists) knew group allocation - not blinded. Participants in the intervention group received additional time with psychiatrists. Psychiatrists received supervision only for participants in the intervention group. Psychiatrists' fidelity to the intervention unclear.
Detection bias (blinding of outcome assessment)	UNCLEAR UNCLEAR	<u>Personnel-measured outcomes</u> Medication Adherence Rating Scale, Working Alliance Inventory-Therapist Version, PANSS, GAF Participants not blinded, assessors blinded. "Assessment was performed by trained psychologists blind to the patient's group assignment". Did not report whether or not there were any blind breaks, and no description of any attempts to counter potential blind breaks.

		<u>Participant-rated outcome measures</u> RAS Participants not blinded, knowledge of group could bias ratings.
Incomplete outcome data	UNCLEAR	Attrition and drop-out not reported Not reported as intention to treat analyses
Selective outcome reporting	UNCLEAR	No pre-registered study protocol.
Other bias	UNCLEAR	117 patients recruited but 33 (28%) refused to participate. Information about non-participants not collected.

Study 4: Green 2013

Entry	Judgement	Support for judgement
Sequence generation	UNCLEAR	No description of method used to generate allocation sequence. "Recruitment was stopped after 38 eligible persons agreed to attend group orientation meetings. Of these, 32 were enrolled and randomly assigned to a cohort"
Allocation concealment	UNCLEAR	No description of method to conceal allocation sequence.
Performance bias (blinding of participants and personnel)	HIGH	All outcomes are self-reported questionnaires Intervention providers not blinded and participants not blinded. Delayed intervention control group.
Detection bias (blinding of outcome assessment)	HIGH	All outcomes are self-reported questionnaires CSI, W-QLI, RAS, PAM-MH, BASIS-24 Participants not blinded and intervention providers not blinded. Did not report blinding of outcome assessors.
Incomplete outcome data	UNCLEAR	28 participants (93%) completed questionnaires at FU 1 – the group allocation or reasons for the 2 missing participants not reported 30 participants (100%) completed questionnaires at FU 2

		Not reported if there was any missing data from the completed questionnaires Reasons for 2 drop-outs before study began not reported Analyses not intention to treat "…32 were enrolled and randomly assigned to a cohort, although two persons dropped out before the study began and were not included in the analyses"
Selective outcome reporting	HIGH	No pre-registered study protocol Data not reported for all outcomes pre-specified in methods section
Other bias	UNCLEAR	500 participants had study information leaflets mailed to them, the first 38 who made contact were invited to a study orientation meeting. 6 did not attend so 32 were randomised.

Study 5: Morrison 2014

Entry	Judgement	Support for judgement
Sequence generation	LOW	"Participants were randomly assigned electronically (1:1) by a computerised system (Open Clinical Data Management System [OpenCDMS], version 1.7.4) with permuted block sizes of four or six, to receive cognitive therapy plus treatment as usual, or treatment as usual alone"
Allocation concealment	LOW	"Because of the variability of TAU, and because this control is dependent on local service configurations and specific sources of referral to the trial, randomisation was first stratified by study site. OpenCDMS then sent out email notifications of the allocations to the therapists and trial manager…..randomisation was independent…..research workers were not involved in the randomisation process"
Performance bias (blinding of participants and personnel)	HIGH	Participants and intervention providers knew treatment allocation - not blinded.

Detection bias (blinding of outcome assessment)	LOW UNCLEAR	<u>Personnel-measured outcomes</u> PANSS & PSYRATS "We used many strategies to achieve masked ratings: research workers were not involved in the randomisation process; therapists were required to consider room use and diary arrangements in view of potential blind breaks; and patients were reminded by assessors not to talk about treatment allocation. 13 blind breaks (representing 18% of participants) were reported by research assistants with a standard form: four (31%) of these breaks were with TAU and nine (69%) with CT. In cases where concealment was broken, another rater assessed the patient for all subsequent assessments or the ratings were discussed with a masked rater and consensus reached. This assessment strategy ensured that only a minority of a total of about 500 assessments had their validity threatened by absence of rater masking". <u>Participant-rated outcome measures</u> QPR, PSP, BDI-PC & SIAS Participants not blinded, knowledge of group could bias ratings.
Incomplete outcome data	HIGH	>25% "Missing data rates of 29.7% at primary endpoint and 29.4% at follow-up"
Selective outcome reporting	LOW	All outcomes are reported as per pre-registered study protocol.
Other bias	UNCLEAR	Not all participants offered FU assessment for 12, 15 and 18 months due to time of entry into study/limited funding. 21 out of 143 participants referred refused to take part in the study, although it is unclear how many would have met eligibility criteria.

Study 6: Salyers 2014

Entry	Judgement	Support for judgement
Sequence generation	UNCLEAR	No description of method used to generate sequence allocation.

		"A total of 118 participants were recruited and randomly assigned to either IMR (N=60) or the PS control group (N=58)".
Allocation concealment	UNCLEAR	No description of method to conceal allocation.
Performance bias (blinding of participants and personnel)	HIGH	Participants and intervention providers not blinded to treatment allocation.
Detection bias (blinding of outcome assessment)	UNCLEAR UNCLEAR	<u>Personnel-measured outcomes</u> PANSS, QLS Outcomes assessors blinded to participant groups. "Participants in both conditions were interviewed at baseline, nine months and 18 months by trained raters blinded to study condition" Did not report whether or not there were any blind breaks, and no description of any attempts to counter potential blind breaks. <u>Participant-rated outcome measures</u> RAS Participants & intervention providers not blinded.
Incomplete outcome data	HIGH	Drop-out rate high (>25%) IMR group: 15 participants (25%) lost at 9 months FU, 22 participants (37%) lost at 18 months FU PS control group: 17 participants (30%) lost a 9 months FU, 24 participants (42%) lost at 18 months FU Reasons for drop-out not reported "Intent to treat analyses compared changes in IMR and PS groups on the outcome measures over time" Analysis used "can accommodate missing data as well as correlated residuals by selecting appropriate covariance structures with maximum likelihood estimation".
Selective outcome reporting	UNCLEAR	All expected outcomes in the methods section are reported as planned, but no pre-registered study protocol.

Other bias	UNCLEAR	123 were eligible for study participation. 5 (4%) chose not to take part.

Study 7: Jorgensen 2015

Entry	Judgement	Support for judgement
Sequence generation	LOW	"A statistician with no connection to the trial established randomisation. An external person packed opaque sealed sequentially numbered envelopes with the assigned treatment" "Participants were randomized 1:1 in blocks of 6 persons"
Allocation concealment	LOW	"The randomization list was then sealed in an opaque envelope that was not opened until the trial was completed"
Performance bias (blinding of participants and personnel)	HIGH	Participants and intervention providers not blinded to treatment allocation. Same clinicians offering TAU + intervention and TAU alone – possible crossover effects. No. and duration of sessions offered to participants in both groups was the same – the intervention was included in ordinary visits.
Detection bias (blinding of outcome assessment)	HIGH	<u>Personnel-measured outcomes</u> PANSS subscales, clinician-rated clinical insight, GAF-F & GAF-S "The first author administered all clinician-administered assessments, but was blind to participants' self-ratings" "The first author was trained using a series of 'gold-standard' videotapes and conducted consensus ratings with the MHCPs on 10% of the PANSS ratings". Rater not blinded to treatment allocation. <u>Participant-rated outcome measures</u>

	UNCLEAR	BCIS, IS, RAS, RSES, GAF-S & GAF-F Participants not blinded, knowledge of group could bias ratings.
Incomplete outcome data	LOW	Low drop-out rate – only 8% total drop-out 5 participants (10% no. randomised) in intervention group lost to FU 3 participants (6% no. randomised) in control group lost to FU Reported reasons for dropout not related to outcome (5/8 reasons stated) Intention to treat analyses "Multiple imputation was applied on missing outcome data" "Twenty imputations were estimated for each missing value"
Selective outcome reporting	LOW	All outcomes are reported as per pre-registered study protocol.
Other bias	UNCLEAR	High refusal rate of study participation. 204 met eligibility criteria, but 103 (50%) refused to take part in the study.

Study 8: Slade 2015

Entry	**Judgement**	**Support for judgement**
Sequence generation	LOW	<u>Team level:</u> "Teams were allocated equally to usual treatment plus the REFOCUS intervention or to usual treatment alone (control), stratified by allocation wave to the four SLaM boroughs and two 2gether localities to ensure balance. Block randomisation of teams was undertaken by the independent Mental Health and Neuroscience Clinical Trials Unit" <u>Participant level:</u> Report states: "For each team, the screened cases of potentially eligible patients were randomly ordered, according to procedures set out by the Mental Health and Neuroscience Clinical Trials Unit, and were recruited in the order of that list"

		Study protocol states: “In SLaM, two randomly ordered lists of service users with a psychosis diagnosis on the caseload of the team will be generated using a random number table
Allocation concealment	LOW	Study protocol states: “All randomisation will be undertaken by the research team following procedures set out by the independent Clinical Trials Unit which has been awarded full CTU registration by UKCRC. Identifying information about teams or service users will not be known before randomisation”
Performance bias (blinding of participants and personnel)	HIGH	“Participating staff, patients and researchers were aware of allocation status” Study protocol states: “Baseline data from staff and service users will as far as feasible be collected before allocation, to avoid bias based on allocation status”
Detection bias (blinding of outcome assessment)	HIGH UNCLEAR UNCLEAR	<u>Personnel-measured outcomes</u> BPRS Report states “Researchers rated symptoms with the brief psychiatric rating scale” <u>Staff-rated measures</u> GAF <u>Participant-rated outcome measures</u> QPR, MANSA, MHCS Report states: Data were collected by researchers who were trained in all measures”. Study protocol states: “Follow up data will where possible be collected by CSOs from the National Institute for Health Research Mental Health Research Network (MHRN). This will increase the likelihood of rater blindness.”
Incomplete outcome data	HIGH	Missing data >25%

		Intervention: 27.1% participants lost to follow-up/missing data Control condition: 25.4% participants lost to follow-up/missing data Reasons for attrition stated (refused, lost contact, too unwell, died) and similar across groups – 3 patients died in each group, 2 patients had missing data from each group Study protocol states: "All included service users will be followed up and included in the analysis using intention-to-treat approaches, reducing the impact of selective attrition"
Selective outcome reporting	LOW	All outcomes are reported as per pre-registered study protocol.
Other bias	UNCLEAR	High refusal rate for study participation. 668 participants met eligibility criteria but 265 (40%) refused to take part in the study.

Study 9: Morrison 2016

Entry	Judgement	Support for judgement
Sequence generation	LOW	"Participants were randomly assigned electronically (1:1) by an administrator using the computerised system Sealed Envelope with permuted block sizes of four, six, and eight to receive CT plus TAU and monitoring, or to TAU plus monitoring."
Allocation concealment	LOW	"Email notifications of the allocation were sent to trial therapists and the trial's principal investigator. The trial assessor was independent of the randomisation process and blind to group allocation in order to facilitate unbiased rating of a semi-structured interview measure of stigma (SIMS: a measure developed specifically for this study) at the baseline, 4 and 7 month follow-ups"

Performance bias (blinding of participants and personnel)	HIGH	Participants and intervention providers knew treatment allocation - not blinded.
Detection bias (blinding of outcome assessment)	LOW UNCLEAR	<u>Personnel measured outcomes</u> SIMS "The trial assessor was independent of the randomisation process and blind to group allocation in order to facilitate unbiased rating of a semi-structured interview measure of stigma (SIMS: a measure developed specifically for this study) at the baseline, 4 and 7 month follow-ups. Several procedures were used to protect the blind: therapists had separate office space from the trial assessor; therapists and the trial assessor were required to consider diary arrangements in view of potential blind breaks; and participants were reminded not to talk about treatment allocation with the trial assessor. Two blind breaks occurred (7% of the sample), both involving participants in TAU and were reported using a standard form." <u>Participant-rated outcome measures</u> QPR-SF, KSS, BDI-7, BHS, SIAS, SER-S, ISS Participants not blinded, knowledge of group could bias ratings.
Incomplete outcome data	LOW	<25% "Missing data rates of 10.3% at 4 months and 6.9% at 7 months"
Selective outcome reporting	UNCLEAR	The study protocol was not pre-registered on a trial registry.
Other bias	UNCLEAR	54 participants were referred, 16 (30%) refused to take part although it is unclear how many of these would have met the eligibility criteria. Nine who had agreed to assessments of eligibility were confirmed as not meeting criteria.

Study 10: Schnackenberg 2016

Entry	Judgement	Support for judgement
Sequence generation	UNCLEAR	Method used to generate the allocation sequence not described in sufficient detail. "Participants were randomised in blocks of two (one control group, one intervention group). Thus, where possible, every participating MHP had one person to support in the intervention and one to support in the control group, respectively, to minimise therapist-specific effects."
Allocation concealment	UNCLEAR	No description of method to conceal the allocation sequence.
Performance bias (blinding of participants and personnel)	HIGH	Participants and intervention providers knew treatment allocation - not blinded.
Detection bias (blinding of outcome assessment)	HIGH HIGH	<u>Personnel-measured outcomes</u> BPRS-E & PSYRATS auditory hallucinations scale "Assessments were conducted by the respective MHP delivering the intervention, as identifying and engaging in the full extent of the voice hearing experience was best considered possible within a trusted, non-pathologising relationship. While blinding is difficult to achieve in reality as language used might unintentionally betray VH group allocation, it has the advantage of reducing potential raters' bias and social desirability responses by participants, as evidenced by lowered effect sizes in blinded CBTp trials. Given the feasibility focus of this study, participant safety and trust appeared to outweigh study design purity at that stage, and a non-blinding process was therefore chosen." <u>Participant-rated outcome measures</u> QPR Participants and outcome assessors not blinded, knowledge of group could bias ratings.

Incomplete outcome data	HIGH	Missing data >25% Analysis was not performed on an ITT basis: "Missing data were followed up and a complete case analysis was conducted." "Only 12 completed all three post-baseline assessment point measures, due to staff shortages (4), staff sickness (2), moving house (1), and no benefits felt (3 TAU clients). Attrition bias was kept low as the same number (5) of participants respectively in the EFC and TAU group did not complete the study. This was further supported by comparing completers and non-completers with a series of independent t-tests on baseline outcome measures and demographic variables."
Selective outcome reporting	HIGH	No pre-registered study protocol. Publication indicates that not all pre-planned outcomes are reported: "As a result of the word limit, only clinically significant and relevant findings could be included in this article"
Other bias	UNCLEAR	Forty-two VH were screened, 29 met inclusion criteria, and 22 finally agreed to continue with the study following randomisation. Reasons given by the 7 VH not to continue with the study following randomisation were: (1) a fear of not being discharged if they talked about voices (n=1); (2) only wanting to take part in the opposite groups to the respective groups they had been randomised into (n=2 and n=1 respectively); (3) dying of a heart attack, despite being below 30 years of age (n=1); (4) focusing on a new relationship instead (n=1); (5) no reasons given (n=1)."

Appendix 6 – Research Ethics Committee Letter of approval

Lothian NHS Board

South East Scotland Research Ethics Committee 01

Waverley Gate
2-4 Waterloo Place
Edinburgh
EH1 3EG
Telephone 0131 536 9000

www.nhslothian.scot.nhs.uk

Date 16 June 2015
Your Ref
Our Ref

Enquiries to: Sandra Wyllie
Extension: 35473
Direct Line: 0131 465 5473
Email: Sandra.Wyllie@nhslothian.scot.nhs.uk

Miss Helen Lynch
Trainee Clinical Psychologist
NHS Borders

Dear Miss Lynch

Study title: **The role of self-stigma in treatment decision-making capacity and recovery in psychosis**
REC reference: **15/SS/0025**
IRAS project ID: **164162**

Thank you for your letter of 08 June 2015, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Vice-Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager, Mrs Sandra Wyllie, sandra.wyllie@nhslothian.scot.nhs.uk. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Appendix 6 – Research Ethics Committee Letter of approval

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Appendix 6 – Research Ethics Committee Letter of approval

Document	*Version*	*Date*
Copies of advertisement materials for research participants [Study Poster V.2]	2	03 June 2015
Covering letter on headed paper [Cover Letter Response to Provisional Opinion]	1	08 June 2015
GP/consultant information sheets or letters [GP Letter V.2]	2	03 June 2015
Interview schedules or topic guides for participants [Positive and Negative Syndrome Scale (PANSS)]	1	27 January 2015
Interview schedules or topic guides for participants [MacArthur Competence Assessment Tool for Treatment (MacCAT-T)]	1	27 January 2015
Interview schedules or topic guides for participants [Interview Guide for PANSS V.1]	1	02 June 2015
Other [Summary CV for Supervisor (Mike Henderson)]	1	30 January 2015
Other [Referrer Information Sheet V.2]	2	22 May 2015
Other [Demographics Form V.1]	1	21 May 2015
Other [Information Collection Card V.1]	1	22 May 2015
Participant consent form [Participant Consent Form V.2]	2	22 May 2015
Participant information sheet (PIS) [Participant Information Sheet V.2]	2	22 May 2015
REC Application Form [REC_Form_27012015]		27 January 2015
Research protocol or project proposal [Study Protocol V.2]	2	21 May 2015
Summary CV for Chief Investigator (CI) [Helen Lynch CV]	1	27 January 2015
Summary CV for supervisor (student research) [Paul Hutton CV]	1	27 January 2015
Validated questionnaire [Internalised Stigma of Mental Illness Inventory (ISMI) V.2]	2	03 June 2015
Validated questionnaire [Recovery Assessment Scale (RAS) V.2]	2	03 June 2015
Validated questionnaire [DASS-21 Questionnaire V.2]	2	03 June 2015

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol

Appendix 6 – Research Ethics Committee Letter of approval

- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

15/SS/0025	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Yours sincerely

Dr Chee Wee Tan
Vice Chair

Email:sandra.wyllie@nhslothian.scot.nhs.uk

Enclosures: "After ethical review – guidance for researchers"

Copy to: *Mrs Jo-Anne Robertson*
Ms Joy Borowska, NHS Borders Research and Development

Appendix 7 – Study poster

RESEARCH STUDY

Do you want to help us understand more about the impact of psychosis?

NHS Borders and the University of Edinburgh are carrying out a study looking at the relationship between how a person feels about their mental health condition and the treatment they receive in mental health services.

Who can take part?

People aged 18-65 with a diagnosis of schizophrenia, schizoaffective or delusional disorder.

What will it involve?

An interview with the researcher and completion of some questionnaires.

If you would like to be emailed an information sheet about the study, or are interested in taking part, please contact the researcher, Helen Lynch, Trainee Clinical Psychologist (NHS Borders/University of Edinburgh). Please tear off a slip below with contact details.

Appendix 8 – Participant Information Sheet

Participant Information Leaflet

Study: Self-stigma, treatment decision-making capacity and recovery in psychosis

Researcher: Helen Lynch, Trainee Clinical Psychologist

REC Reference Number: 15-SS-0025

We would like to invite you to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it will involve for you. Please take time to read the following information carefully and discuss it with others if you wish. If you are interested in the study, the researcher will contact you and answer any questions you may have before you make your decision.

What is the purpose of the study?
We are interested in studying the relationship between unhelpful beliefs people might have about mental health problems, ability to make decisions about treatment and recovery from psychosis.

Why have I been invited to take part?
You have been invited to take part because you are aged 18-65, have a primary diagnosis of psychosis, and live within the NHS Borders health board area.

Do I have to take part?
No - it is completely up to you whether or not you would like to take part. If you are interested, you will be asked for a contact number and a convenient time for the researcher to contact you to talk about the study and answer any of your questions. You will be given at least 24 hours to review this information leaflet before the researcher makes contact with you. If you decide that you want to take part, the researcher will arrange a meeting with

you when you will be asked to sign a consent form and only then will we go ahead with the study. You are free to not take part or to stop taking part at any point in the study, without giving a reason. Whatever you decide, your normal care will not be affected.

What will taking part involve?
We expect that your participation in the study could last up to two and a half hours. You may choose to have this carried out over more than one occasion.

The researcher will ask you some questions about mental health problems. There will be an interview and some questionnaires focused on:

- Your own experience of mental health problems.
- Your views about mental health problems.
- Your ability to make decisions about treatment.

If you have any difficulties with reading then the researcher will read the questionnaires out to you. The researcher will ask your permission to make an audio recording so that the interview can be listened to by the researcher and scored.

You can have breaks during the interview as and when you want them. You can choose to stop taking part or postpone the interview to another day.

Where will it be held?
We will be able to meet you at your local Community Mental Health Team (CMHT) base, GP surgery or hospital. We will meet you wherever is easiest for you. We may be able to visit you at home if you are not able to travel. If you wish to be seen at home, before coming to visit you, we will need your consent for your mental health care team to share with us any necessary information about risk that may be held on your file.

What happens next?
After the study, we will give you time to ask any questions and talk about what it was like for you taking part. You will be offered the choice to receive a summary of the study's findings that will be produced once the study is finished in May 2016. You can also choose to review and contribute to this summary if you would be interested in doing so.

Confidentiality
Once we have your permission, we will inform your care team and GP that you are taking part in the study. Information collected about you during the study will **not** be fed back or exchanged unless you ask us to. The only time the researcher may need to share information would be if you disclosed

something that gave the researcher concerns about your or others' safety, in order to keep you and others safe. The researcher would discuss this with you at the time if this happens. If you have any questions about this, please do ask the researcher.

What will happen to my data?
Your name and contact details will be stored securely by the researcher in a locked cabinet on NHS premises and then destroyed once the study is finished in May 2016. The data we collect from you during the study will be anonymised. It will be stored in an encrypted (i.e. scrambled) format on an NHS computer for the duration of the study, and afterwards at the University of Edinburgh. You can ask for your data to be removed from the study until the point that the results are published. After this time it will not be possible to remove your data from the study. The results from this study are likely to be published in scientific journals and used in presentations with the wider research and NHS communities. However, as the data will be anonymised you will not be able to be identified. Your results from the study will therefore remain confidential.

Your data and consent form may be examined by responsible individuals who carry out audits in the NHS. This is usual practice to make sure that research is being carried out responsibly. With this exception, your data will only ever be made available to the research team.

What are the benefits and disadvantages to me of taking part?
Your participation and feedback will help us understand better how beliefs about mental illness may affect a person's involvement in their treatment and recovery from psychosis. This could help to improve how we provide mental health services in the future. Taking part is unlikely to benefit you directly, however you can ask for your assessment information to be shared with your care team to help clarify your care needs.

It is possible that you may find the interview and questionnaires tiring. We might ask you things that you find upsetting (e.g. mental health problems). You will be free to stop the interview at any point. You can have as many short breaks as you need or split the testing over two dates if you prefer.

What if I need emotional support following the study?
If you feel you need listening and emotional support, you may wish to contact the free, confidential helplines listed below:

Samaritans
24 hour support.
Tel: 08457 90 90 90

Textphone: 08457 90 91 92
Email helpline: jo@samaritans.org
Website: http://www.samaritans.org/

Breathing Space
Tel: 0800 83 85 87
Website: http://www.breathingspacescotland.co.uk/

Borderline
Local mental health helpline offering an emotional support and listening service.
Tel: 0800 027 4466

If you notice a significant decline in your mental health following your participation in the study we would recommend that you contact your GP.

Expenses and payments
We will refund your travel expenses if you drive or use public transport to travel from your home to take part in the study. Please keep your receipts for this journey if you do travel by public transport. For more information about this, please contact the researcher. Please note that it could take up to a month to receive your reimbursement.

We are unable to offer any payments to people for taking part.

Who is organising and funding the study?
The research has been designed and is being carried out by a Trainee Clinical Psychologist undertaking a Doctorate in Clinical Psychology at the University of Edinburgh. The study is being supervised by Dr Paul Hutton (Clinical Psychologist, University of Edinburgh) and Mr Mike Henderson (Consultant Clinical Psychologist, NHS Borders). Funding and sponsorship has been provided by the University of Edinburgh.

Who has reviewed the study?
This study has been reviewed and approved by a NHS Ethics Committee and NHS Borders Research and Development.

Who can I contact if I have a complaint?
You are free to discuss any concerns about the study with the researcher (contact details at the end of this leaflet) who will do her best to assist you. If you remain unhappy and wish to complain formally, you can do this by contacting:

NHS Borders Feedback and Complaints Team
Borders General Hospital
Melrose TD6 9BS

Email: complaints.clingov@borders.scot.nhs.uk
Telephone: 01896 826719

In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the relevant NHS organisation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Who can I contact about this study?
If you would like any further information about the study or think you might like to take part, please contact the researcher:

Helen Lynch, Trainee Clinical Psychologist, NHS Borders
Email: helenlynch2@nhs.net
Work mobile: 07775 227 129

If you prefer, you can ask a member of your care team to contact the researcher on your behalf.

You are also free to discuss the study or any issues around participating in research with the study's supervisors. Dr Paul Hutton (Clinical Psychologist, University of Edinburgh) can be contacted on 0131 651 3972, and Mr Mike Henderson (Consultant Clinical Psychologist, NHS Borders) on 01896 827151.

If you would prefer to speak to someone who is not a member of the research team but who can answer questions more generally about taking part in research, please contact Joy Borowska (Research Governance Co-ordinator, NHS Borders) on 01896 826717.

Thank you for taking the time to read this information leaflet.

Appendix 9 – Participant Consent Form

Study Number: 15-SS-0025

Participant Identification Number for this trial:

CONSENT FORM

Title of Project: *The role of self-stigma in treatment decision-making capacity and recovery in psychosis*

Lead Researcher: *Helen Lynch, Trainee Clinical Psychologist*

Please initial box

1. I confirm that I have read the Participant Information Leaflet dated 22/05/2015 (Version 2) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. ☐

3. I agree to my General Practitioner and/or mental health care team being informed of my participation in the study. ☐

4. I understand that relevant sections of data collected during the study may be looked at by individuals from the regulatory authorities and from the Sponsor(s) (NHS Lothian and the University of Edinburgh) or from the other NHS Board(s) where it is relevant to my taking part in this research. I give permission for those individuals to have access to my records. ☐

5. All the information I provide in the study will be anonymous and confidential. However, I understand that if I reveal information about future harm to myself, or others, that information will be passed onto the appropriate healthcare professional. ☐

6. If wishing to be seen at home, I agree that my care team can share with the researcher information from the risk assessment that is held in my patient file. ☐

7. I agree to being audio recorded as part of the study. ☐

8. I agree to take part in this study. ☐

Signed:

Name of Participant	Date	Signature
Name of Person taking consent	Date	Signature

Original (x1) to be retained in site file. Copy (x1) to be retained by the participant.

Appendix 10 - Demographics Form

Additional Information Sheet – please complete

Age: _____ **Gender:** *(please circle)* Male / Female

What is your relationship status? *(please circle)*

Single / Married / In a relationship / Divorced / Widowed / Other *(please state)*
_____

Please provide the first part plus one digit of your postcode:
(e.g. if your postcode was TD1 1PF, you would put TD1 1)

_____

What is your ethnic group? Please tick the box most relevant to you

	White British
	White other
	Asian British
	Asian other

	Black British
	Black other
	Any other (please specify) _____

Employment status: *(please circle)*

Employed / Unemployed / Student / Retired /

Unable to work (please specify reason) _____

Diagnosis:

_____

Duration of illness:

_____

Current medication(s):

_____

Thank you for taking the time to complete this form.

Appendix 11 - Internalised Stigma of Mental Illness Inventory (ISMI) (Ritsher et al., 2003)

Internalised Stigma of Mental Illness Inventory (ISMI)

Participant No: _____ **Date:_____**

We are going to use the term “mental illness” in the rest of this questionnaire, but please think of it as whatever you feel is the best term for it.

For each question, please mark whether you strongly disagree (1), disagree (2), agree (3), or strongly agree (4).

	Strongly Disagree	Disagree	Agree	Strongly Agree
1. I feel out of place in the world because I have a mental illness.	1	2	3	4
2. Mentally ill people tend to be violent.	1	2	3	4
3. People discriminate against me because I have a mental illness.	1	2	3	4
4. I avoid getting close to people who don’t have a mental illness to avoid rejection.	1	2	3	4
5. I am embarrassed or ashamed that I have a mental illness.	1	2	3	4
6. Mentally ill people shouldn’t get married.	1	2	3	4
7. People with mental illness make important contributions to society.	1	2	3	4
8. I feel inferior to others who don’t have a mental illness.	1	2	3	4
9. I don’t socialise as much as I used to because my mental illness might make me look or behave “weird.”	1	2	3	4

	Strongly Disagree	Disagree	Agree	Strongly Agree
10. People with mental illness cannot live a good, rewarding life.	1	2	3	4
11. I don't talk about myself much because I don't want to burden others with my mental illness.	1	2	3	4
12. Negative stereotypes about mental illness keep me isolated from the "normal" world.	1	2	3	4
13. Being around people who don't have a mental illness makes me feel out of place or inadequate.	1	2	3	4
14. I feel comfortable being seen in public with an obviously mentally ill person.	1	2	3	4
15. People often patronise me, or treat me like a child, just because I have a mental illness.	1	2	3	4
16. I am disappointed in myself for having a mental illness.	1	2	3	4
17. Having a mental illness has spoiled my life.	1	2	3	4
18. People can tell that I have a mental illness by the way that I look.	1	2	3	4
19. Because I have a mental illness, I need others to make most decisions for me.	1	2	3	4
20. I stay away from social situations in order to protect my family or friends from embarrassment.	1	2	3	4
21. People without mental illness could not possibly understand me.	1	2	3	4

	Strongly Disagree	Disagree	Agree	Strongly Agree
22. People ignore me or take me less seriously just because I have a mental illness.	1	2	3	4
23. I can't contribute anything to society because I have a mental illness.	1	2	3	4
24. Living with mental illness has made me a tough survivor.	1	2	3	4
25. Nobody would be interested in getting close to me because I have a mental illness.	1	2	3	4
26. In general, I am able to live my life the way I want to.	1	2	3	4
27. I can have a good, fulfilling life, despite my mental illness.	1	2	3	4
28. Others think that I can't achieve much in life because I have a mental illness.	1	2	3	4
29. Stereotypes about the mentally ill apply to me.	1	2	3	4

End of Questionnaire. Thank You.

Appendix 12 - Recovery Assessment Scale (RAS) (Giffort et al., 1995)

Recovery Assessment Scale

Participant ID No:_____ **Date:**_____

Instructions: Below is a list of statements that describe how people sometimes feel about themselves and their lives. Please read each one carefully and circle the number to the right that best describes the extent to which you agree or disagree with the statement. Circle only one number for each statement and do not skip any items.

	Strongly Disagree	Disagree	Not sure	Agree	Strongly Agree
1. I have a desire to succeed	1	2	3	4	5
2. I have my own plan for how to stay or become well	1	2	3	4	5
3. I have goals in my life that I want to reach	1	2	3	4	5
4. I believe I can meet my current personal goals	1	2	3	4	5
5. I have a purpose in life	1	2	3	4	5
6. Even when I don't care about myself, other people do	1	2	3	4	5
7. I understand how to control the symptoms of my mental illness	1	2	3	4	5
8. I can handle it if I get sick again	1	2	3	4	5
9. I can identify what triggers the symptoms of my mental illness	1	2	3	4	5
10. I can help myself become better	1	2	3	4	5

	Strongly Disagree	Disagree	Not sure	Agree	Strongly Agree
11. Fear doesn't stop me from living the way I want to	1	2	3	4	5
12. I know that there are mental health services that do help me	1	2	3	4	5
13. There are things that I can do that help me deal with unwanted symptoms	1	2	3	4	5
14. I can handle what happens in my life	1	2	3	4	5
15. I like myself	1	2	3	4	5
16. If people really knew me, they would like me	1	2	3	4	5
17. I am a better person than before my experience with mental illness	1	2	3	4	5
18. Although my symptoms may get worse, I know I can handle it	1	2	3	4	5
19. If I keep trying, I will continue to get better	1	2	3	4	5
20. I have an idea of who I want to become	1	2	3	4	5
21. Things happen for a reason	1	2	3	4	5
22. Something good will eventually happen	1	2	3	4	5
23. I am the person most responsible for my own improvement	1	2	3	4	5
24. I'm hopeful about the future	1	2	3	4	5

	Strongly Disagree	Disagree	Not sure	Agree	Strongly Agree
25. I continue to have new interests	1	2	3	4	5
26. It is important to have fun	1	2	3	4	5
27. Coping with my mental illness is no longer the main focus of my life	1	2	3	4	5
28. My symptoms interfere less and less with my life	1	2	3	4	5
29. My symptoms seem to be a problem for shorter periods of time each time they occur	1	2	3	4	5
30. I know when to ask for help	1	2	3	4	5
31. I am willing to ask for help	1	2	3	4	5
32. I ask for help, when I need it	1	2	3	4	5
33. Being able to work is important to me	1	2	3	4	5
34. I know what helps me get better	1	2	3	4	5
35. I can learn from my mistakes	1	2	3	4	5
36. I can handle stress	1	2	3	4	5
37. I have people I can count on	1	2	3	4	5
38. I can identify the early warning signs of becoming sick	1	2	3	4	5
39. Even when I don’t believe in myself, other people do	1	2	3	4	5

40. It is important to have a variety of friends	1	2	3	4	5
	Strongly Disagree	Disagree	Not sure	Agree	Strongly Agree
41. It is important to have healthy habits	1	2	3	4	5

End of Questionnaire. Thank You.

Appendix 13 – MacArthur Competence Assessment Tool for Treatment (MacCAT-T) (Grisso et al., 1995) Interview Schedule

I am going to ask you some questions about a possible, hypothetical treatment. This discussion is just for the purpose of this interview and will not affect your actual treatment. First, I will describe to you what I believe is the problem. Then I'll talk to you about the research treatment, and the possible risks and benefits. I will ask you to apply that information to yourself, and then I'll ask you to make a decision about whether you would or would not want to take this medication if it were offered to you.

Understanding disorder

Disclosure

- Diagnosis
- Feature of disorder
- Feature of disorder
- Feature of disorder
- Course of disorder

Now please explain in your own words what I've said about your condition.

Re-disclose and re-enquire if necessary.

Appreciation-disorder

Now that is what I think is the problem in your case. If you have any reason to doubt that, I'd like you to tell me so. What do you think?

Understanding-treatment

Disclosure

1. Name of treatment: Medicine 1
2. Feature of treatment: It can be taken as tablets or liquids twice a day
3. Feature of treatment: You will start at a low dose and increase until we find the right dose for you.
4. Feature of treatment: You ought to stay on the medication for at least 2 years and see your doctor once a month

Now please explain in your own words what I've said about this treatment

Re-disclose and re-enquire if necessary.
Understanding-benefits/risks

Disclosure

1. Benefit: It will make your symptoms less troublesome

2. Benefit: It will reduce the risk of relapse. With treatment 15% relapse. Without treatment 57% relapse

3. Risk: There is a low risk that you may experience problems such as abnormal movements of your mouth and tongue, which you cannot control.

4. Risk: There is a moderate risk that you may experience problems with weight gain

Now please explain in your own words what I've said about benefits and risks of this treatment.

Re-disclose and re-enquire if necessary.

Appreciation-treatment

You might or might not decide that this is the treatment you want – we'll talk about it later. But do you think it's possible that this treatment might be of some benefit to you?

So you feel that it is / isn't possible for this treatment to be of some help for your condition. Can you explain that to me? What makes it seem that the treatment would / wouldn't be of possible benefit to you?

Alternative treatments

Disclosure

1. Name of treatment: No treatment

2. Feature of treatment: You do not have to take any tablets

3. Feature of treatment: You will need to continue seeing a doctor or nurse or psychologist every month

4. Feature of treatment: You ought to continue attending the service for at least 2 years

Now please explain in your own words what I've said about this treatment

*Re-disclose and re-enquire if necessary.***Understanding-benefits/risks**

Disclosure

1. Benefit: You do not have to take any tablets.

2. Benefit: There is no risk of weight gain.

3. Risk: The likelihood is your symptoms will continue without treatment

4. Risk: There is a high risk of relapse. Without treatment 57% of patients relapse within a year.

Now please explain in your own words what I've said about benefits and risks of this treatment.

Re-disclose and re-enquire if necessary.

First choice and reasoning

Now let's review the choices that you have. First ....: second..... Which of these seems best for you? Which do you think you would be most likely to want?

You think that (state patient's choice) might be best. Tell me what it is that makes that seem better than the others.

Discuss explanation to explore reasoning process.

Generate consequences

I told you about some of the possible benefits and risks or discomforts of (name the patient's preferred treatment option). What are some ways that these might influence your everyday activities at home or at work?

Now let's consider (no-treatment option). What are some ways that the outcomes of that option might influence your everyday activities at home or at work?

Final choice

When we started this discussion you favoured (insert First Choice from earlier enquiry, or note that the patient seemed to be having difficulty deciding). What do you think now that we have discussed everything? Which would you want to do?

Logical consistency of choice

Examiner's explanation.

Appendix 14 - Depression Anxiety Stress Scales - 21 Item Version (DASS-21, Lovibond & Lovibond, 1995)

DASS21

Participant No: *Date:*

Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you *over the past week*. There are no right or wrong answers. Do not spend too much time on any statement.

The rating scale is as follows:
0 Did not apply to me at all
1 Applied to me to some degree, or some of the time
2 Applied to me to a considerable degree, or a good part of time
3 Applied to me very much, or most of the time

1	I found it hard to wind down	0	1	2	3
2	I was aware of dryness of my mouth	0	1	2	3
3	I couldn't seem to experience any positive feeling at all	0	1	2	3
4	I experienced breathing difficulty (eg, excessively rapid breathing, breathlessness in the absence of physical exertion)	0	1	2	3
5	I found it difficult to work up the initiative to do things	0	1	2	3
6	I tended to over-react to situations	0	1	2	3
7	I experienced trembling (eg, in the hands)	0	1	2	3
8	I felt that I was using a lot of nervous energy	0	1	2	3
9	I was worried about situations in which I might panic and make a fool of myself	0	1	2	3
10	I felt that I had nothing to look forward to	0	1	2	3
11	I found myself getting agitated	0	1	2	3
12	I found it difficult to relax	0	1	2	3
13	I felt down-hearted and blue	0	1	2	3
14	I was intolerant of anything that kept me from getting on with what I was doing	0	1	2	3
15	I felt I was close to panic	0	1	2	3
16	I was unable to become enthusiastic about anything	0	1	2	3
17	I felt I wasn't worth much as a person	0	1	2	3
18	I felt that I was rather touchy	0	1	2	3
19	I was aware of the action of my heart in the absence of physical exertion (eg, sense of heart rate increase, heart missing a beat)	0	1	2	3

20	I felt scared without any good reason	0	1	2	3
21	I felt that life was meaningless	0	1	2	3

Appendix 15 – Bootstrapped 95% confidence intervals (CI) for all variables included in the analysis

	ISMI	ISMI - SR	RAS	DASS	MacCAT understand	MacCAT apprec.	MacCAT reason	MacCAT choice	PANSS positive	PANSS negative	PANSS cognitive	PANSS excitement	PANSS emotion
ISMI	-												
ISMI – SR	0.976 0.995**	-											
RAS	-0.755 -0.252**	-0.734 0.217*	-										
DASS	0.312 0.791**	0.345 0.800**	-0.676 0.042	-									
MacCAT understand	-0.415 0.146	-0.434 0.125	-0.354 0.280	-0.521 0.173	-								
MacCAT apprec.	-0.518 0.310	-0.559 0.301	-0.489 0.305	-0.701 0.140	-0.198 0.672	-							
MacCAT reason.	-0.704 -0.082*	-0.684 -0.040*	-0.203 0.579	-0.515 0.100	-0.208 0.726	0.019 0.724*	-						
MacCAT choice	-0.468[b] 0.261[b]	-0.475[b] 0.288[b]	-0.514[b] 0.349[b]	-0.499[b] 0.136[b]	-0.618[b] 0.487[b]	-0.154[b] 0.808[b]*	-0.141[b] 0.656[b]	-					
PANSS positive	-0.050 0.605	-0.021 0.605	-0.556 0.149	0.530 0.869**	-0.680 0.034	-0.738 -0.065*	-0.466 0.194	-0.500[b] 0.038[b]	-				
PANSS negative	0.218 0.740*	0.214 0.738*	-0.672 0.225	0.298 0.830**	-0.287 0.292	-0.439 0.326	-0.494 -0.003	-0.454[b] 0.150[b]	0.116 0.736*	-			
PANSS cognitive	-0.029 0.495	-0.018 0.485	-0.533 0.258	0.459 0.864**	-0.728 0.062*	-0.728 -0.090 *	-0.624 0.109	-0.569[b] 0.015[b]	0.617 0.966**	0.065 0.829*	-		
PANSS excitement	-0.423 0.311	-0.419 0.339	-0.425 0.361	-0.435 0.456	-0.859 -0.042**	-0.603 0.434	-0.713 0.214	-0.574[b] 0.357[b]	-0.143 0.769*	-0.397 0.410	-0.206 0.809*	-	
PANSS emotion	0.470 0.851**	0.434 0.830**	-0.662 –0.051	0.363 0.817**	-0.442 0.210	-0.533 0.225	-0.605 0.143	-0.179[b] 0.331[b]	0.196 0.768**	0.267 0.806**	0.165 0.745*	-0.326 0.393	-

Note: DASS, Depression, Anxiety, Stress Scales 21-item version total scores; ISMI, Internalised Stigma for Mental Illness Inventory total mean item scores; ISMI – SR, ISMI total mean item scores minus stigma resistance items; RAS, Recovery Assessment Scale total scores; MacCAT understand, MacArthur Competence Assessment Tool for Treatment understanding domain scores; MacCAT apprec., MacArthur Competence Assessment Tool for Treatment appreciation domain scores; MacCAT reason, MacArthur Competence Assessment Tool for Treatment reasoning domain scores; MacCAT choice, MacArthur Competence Assessment Tool for Treatment expressing a choice domain scores; PANSS positive, Positive and Negative Syndrome Scale positive symptoms subscale scores; PANSS negative, Positive and Negative Syndrome Scale negative symptoms subscale scores; PANSS cognitive, Positive and Negative Syndrome Scale cognitive symptoms subscale scores; PANSS excitement, Positive and Negative Syndrome Scale excitement subscale scores; PANSS emotion, Positive and Negative Syndrome Scale emotional distress subscale scores.*Correlation is significant at the 0.05 level. **Correlation is significant at the 0.01 level. [a] Unless otherwise noted, bootstrap results are based on 1000 bootstrap samples [b] Based on 971 samples

Appendix 16 – Collinearity statistics for decisional capacity domains by predictor

MacCAT-T domain	Predictor	Collinearity statistics	
		Tolerance	VIF
Understanding	Age	0.621	1.610
	Gender	0.528	1.895
	PANSS cognitive symptoms	0.671	1.489
	PANSS excitement	0.419	2.384
Appreciation	Age	0.596	1.678
	Gender	0.528	1.895
	PANSS cognitive symptoms	0.285	3.512
	PANSS excitement	0.413	2.419
	PANSS positive symptoms	0.300	3.333
Reasoning	Age	0.834	1.199
	Gender	0.855	1.169
	Self-stigma (Total ISMI)	0.642	1.556
	Personal recovery (Total RAS)	0.681	1.469

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